Message

From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY]

Sent: 9/25/2018 11:55:30 AM

To: Cassell, Chris - Christopher L [chris.l.cassell@lowes.com]; Chad H. Howlin [chowlin@lawbc.com];

lbergeson@lawbc.com

Subject: RE: PSS Conference Call **Attachments**: ProductStewardship2018.pptx

Ex. 5 Deliberative Process (DP)

Thanks, Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

P: 202-564-1273

Ex. 6 Personal Phone

beck.nancy@epa.gov

From: Cassell, Chris - Christopher L [mailto:chris.l.cassell@lowes.com]

Sent: Friday, September 21, 2018 12:55 PM

To: Chad H. Howlin <chowlin@lawbc.com>; lbergeson@lawbc.com; Beck, Nancy <Beck.Nancy@epa.gov>; Bolen, Derrick

<bolen.derrick@epa.gov>
Subject: RE: PSS Conference Call

Hi all,

Ex. 5 Deliberative Process (DP)

Chris

Chris Cassell

Director of Corporate Sustainability

W - 704.758.5827

E - <u>chris.l.cassell@lowes.com</u> Connections Profile: <u>Link</u>

-----Original Appointment-----

From: Chad H. Howlin [mailto:chowlin@lawbc.com]
Sent: Thursday, September 20, 2018 11:05 AM

To: Chad H. Howlin; Lynn L. Bergeson; Nancy B. Beck, Ph.D.; Cassell, Chris - Christopher L; 'bolen.derrick@epa.gov'

Subject: PSS Conference Call

When: Friday, September 21, 2018 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where:

Ex. 6 Conference Code

NOTICE: All information in and attached to the e-mails below may be proprietary, confidential, privileged and otherwise protected from improper or erroneous disclosure. If you are not the sender's intended recipient, you are not authorized to intercept, read, print, retain, copy, forward, or disseminate this message. If you have erroneously received this communication, please notify the sender immediately by phone (704-758-1000) or by e-mail and destroy all copies of this message electronic, paper, or otherwise.

By transmitting documents via this email: Users, Customers, Suppliers and Vendors collectively acknowledge and agree the transmittal of information via email is voluntary, is offered as a convenience, and is not a secured method of communication; Not to transmit any payment information E.G. credit card, debit card, checking account, wire transfer information, passwords, or sensitive and personal information E.G. Driver's license, DOB, social security, or any other information the user wishes to remain confidential; To transmit only non-confidential information such as plans, pictures and drawings and to assume all risk and liability for and indemnify Lowe's from any claims, losses or damages that may arise from the transmittal of documents or including non-confidential information in the body of an email transmittal. Thank you.

TOXIC SUBSTANCES CONTROL ACT: EPA IMPLEMENTATON

Product Stewardship 2018 September 29, 2018

Nancy B. Beck, PhD, DABT
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
beck_nancy@epa_gov



The New Law

- "The Frank R. Lautenberg Chemical Safety for the 21st Century Act"
 - Amends and updates the Toxic Substances Control Act (TSCA)
 - o Signed by the President on June 22, 2016
 - o Effective immediately
- Significance
 - o First major update to TSCA in 40 years (1976)
 - Passed with overwhelming bipartisan support in both the U.S. House and Senate
 - Received support from chemical industry and downstream users of chemicals, NGOs, and other stakeholders



The New Law

Impacts:

- TSCA Inventory
- Existing Chemicals Program
- New Chemicals Program

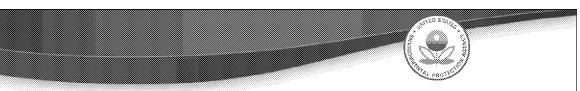


TSCA: Overarching Approach

TSCA Section 2(b)(3):

- Authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation.
- While fulfilling the primary purpose of this Act to assure that such innovation and commerce in such chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment.
- TSCA takes a risk-based approach to chemicals management

4.



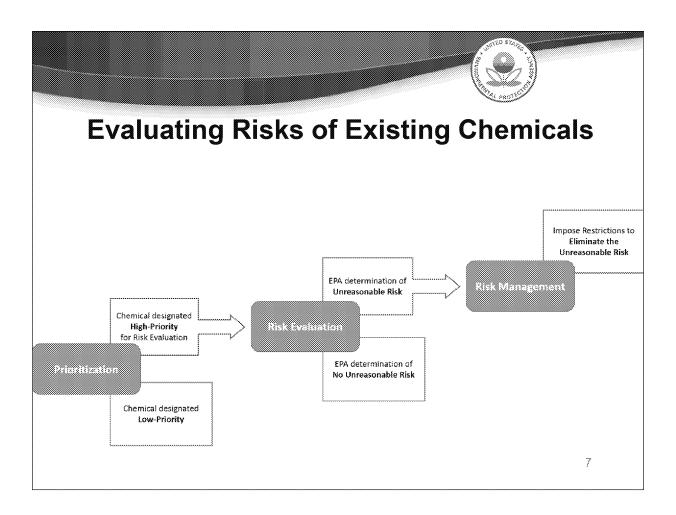
TSCA Inventory for Active/Inactive Chemicals

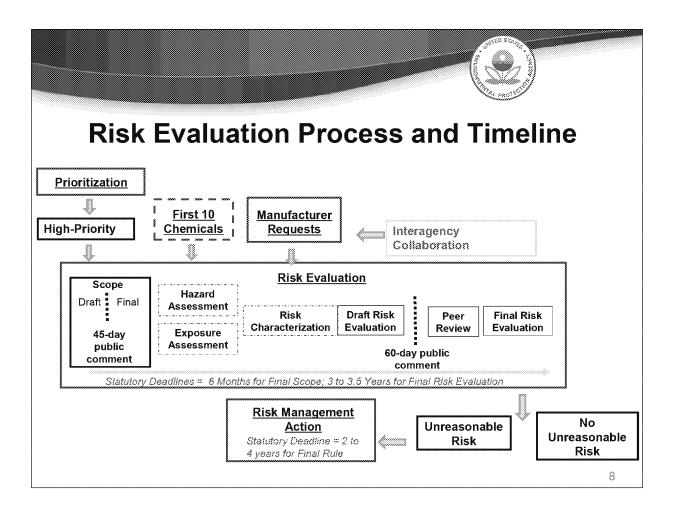
- Industry must report on the chemicals they manufactured in previous 10 years.
 - o Chemicals will be designated as active or inactive
 - Existing Inventory: over 80,000 chemicals (active and inactive)
- Voluntary processor reporting until October 5, 2018.
- Approximately 40,000 chemicals are on the active inventory, so far.



The New Law Changes Related to Existing Chemicals

- Mandatory duty on EPA to evaluate existing chemicals clear and enforceable deadlines
- Chemical assessment is risk-based; without consideration of costs or other non-risk factors
- Persistent, Bioaccumulative and Toxic Chemicals: Fast-track to address certain PBT chemicals already on TSCA Work Plan
- Must consider risks to potentially exposed or susceptible subpopulations identified as relevant to the evaluation
- Unreasonable risks identified in risk evaluation must be addressed
- Expanded authority to more quickly require development of chemical information when needed



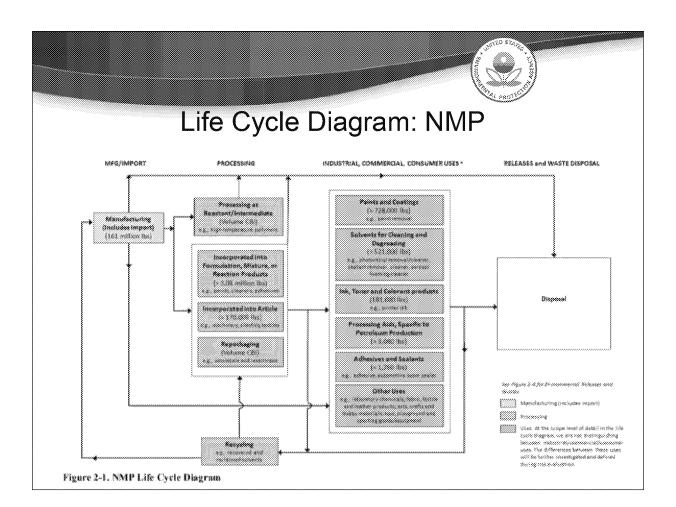


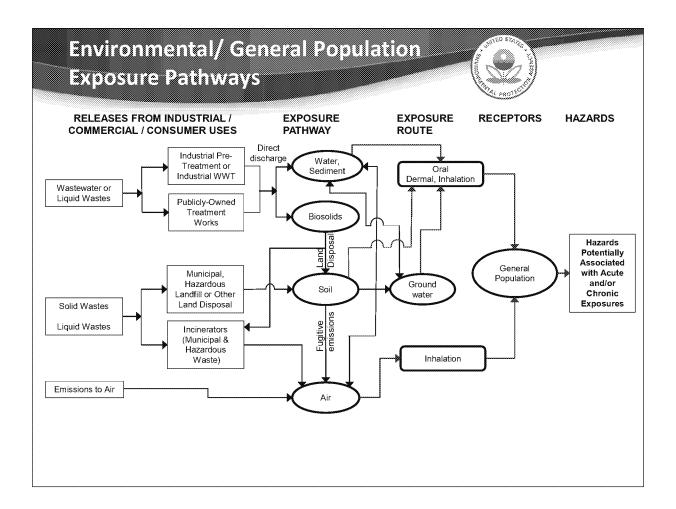


Risk Evaluation: Statutory Requirements

- EPA must follow the framework rule for risk evaluation

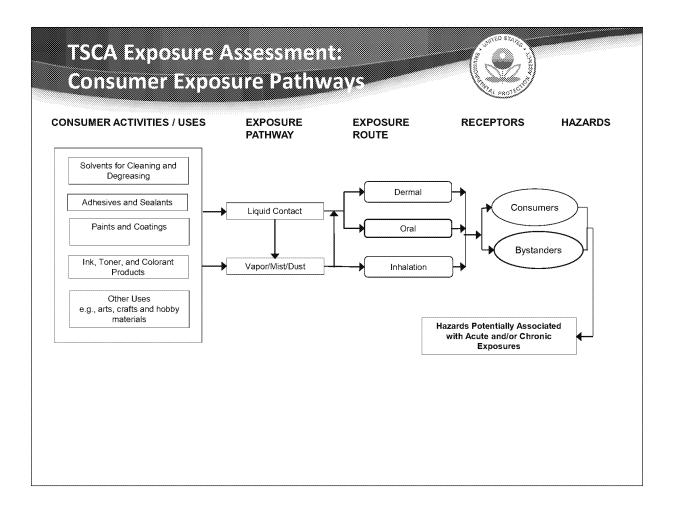
 Determine if a chemical presents an unreasonable risk of injury to
 health or the environment under conditions of use
 - Without consideration of cost or other non-risk factors
 - Including unreasonable risk to potentially exposed or susceptible subpopulation(s) determined to be relevant to the evaluation
- This process must be completed within 3 3.5 years
- For each risk evaluation completed, EPA must designate a new high-priority chemical
- By December of 2019, EPA must have initiated 20 highpriority chemicals for risk evaluation
 - o Additional risk evaluations may come from manufacturer requests





Amended TSCA tasks EPA to consider all possible routes of exposure of a given chemical resulting from its current manufacturing, processing, use and disposal – which can quickly become quite cumbersome as this graphic demonstrates. And yet, the exposure evaluation has to be conducted within the mandated timelines. In order to more efficiently conduct general population exposure estimates, exposure pathways can be eliminated based on the likelihood (or not) of a given exposure pathway for the chemical being evaluated. One way to narrow the scope is to consider the fate properties of a given chemical and the likelihood of being found in particular media. For example, some chemicals currently being evaluated are not anticipated to sorb to sediment or biosolids or soil.

1/7/2021



1/7/2021



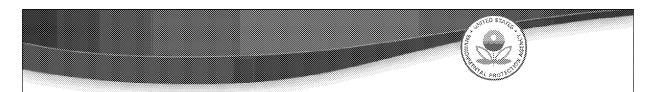
Initial 10 Risk Evaluations

 The list of the initial 10 chemicals was published on Dec. 19, 2016

> 1, 4 Dioxane 1-Bromopropane Asbestos Carbon Tetrachloride Cyclic Aliphatic Bromide Cluster (HBCD)

Methylene Chloride N-Methylpyrolidone Pigment Violet 29 Trichloroethylene Tetrachloroethylene

- Scope documents published June 22, 2017
- Problem Formulation documents published June, 2018
- Risk evaluations must be final by December 2019



Persistent, Bioaccumulative, and Toxic Chemicals

- Statute requires a fast-track process for certain PBT chemicals
- Use and exposure assessment required; No formal risk evaluation
- Rules to reduce exposure, to the extent practicable, must be proposed by June 2019 and finalized 18 months later
- Status
 - 5 chemicals will get expedited action based on use and exposure assessments for these chemicals.
 - o Decabromodiphenyl ether (DecaBDE)
 - o Hexachlorobutadiene (HCBD
 - Pentachlorothiophenol (PCTP)
 - Phenol, isopropylated, phosphate (3:1)
 - o 2,4,6-Tris(tert-butyl) phenol



Overview of New Chemicals Program

TSCA Section 5:

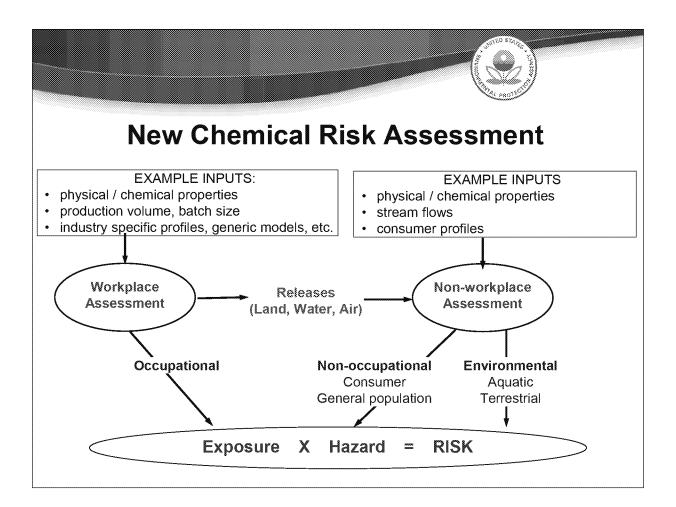
New Chemicals program functions as a "gatekeeper" to help manage the potential risk to human health and the environment from chemicals new to the marketplace

- Anyone who plans to manufacture (or import) a new chemical substance must provide EPA with notice - a Premanufacture Notice (PMN)
- EPA must review and evaluate new chemicals (or significant new uses of existing chemicals) and make an affirmative finding before those chemicals can enter the market
- Review must be completed within 90 days, with ability to extend 90 days
- If risks are identified, EPA must impose restrictions or prohibitions on the manufacturing, processing or use of the chemical to ensure the risks are mitigated

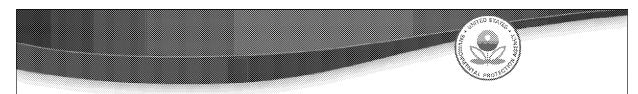


New Chemical Assessments

- New chemicals determinations are made using a risk-based approach, taking into account both hazard and exposure, under the substance's conditions of use (intended, known and reasonably foreseen).
- EPA assesses health and environmental hazards and exposures to:
 - multiple populations of humans: workers, consumers and general population, including susceptible subpopulations, e.g. different age groups of the general population)
 - the environment (e.g., primarily aquatic environment).
- Findings:
 - Presents unreasonable risk
 - May present an unreasonable risk
 - Is not likely to present an unreasonable risk
 - Information insufficient to permit a reasoned evaluation



From previous presentations



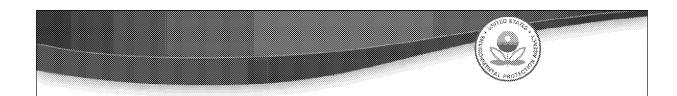
Next-Phase of Implementation Actions (Through Jan., 2020)

Prioritization

- By December 2019, EPA must:
 - Have 20 chemicals designated as high-priority undergoing risk evaluation
 - Have 20 chemicals designated as low-priority (no risk evaluation at this time)

Risk Evaluations

- December 2018 Spring 2019: EPA will publish draft risk evaluations for the first 10 chemicals
 - Public Comment
 - Peer Review
- December 2019 EPA will have completed the risk evaluations on the first 10 chemicals



For More Information

General TSCA: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act

Evaluating Existing Chemicals: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/how-epa-evaluates-safety-existing-chemicals

Reviewing New Chemicals: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca

Contact EPA at

https://www.epa.gov/assessing-and-managing-chemicalsunder-tsca/forms/assessing-and-managing-chemicals-undertsca 19 From: Beck, Nancy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=168ECB5184AC44DE95A913297F353745-BECK, NANCY)

Sent: 6/25/2018 4:27:51 PM

To: Lynn L. Bergeson [lbergeson@lawbc.com]

Subject: RE: 11 AM ET webinar

Ex. 5 Deliberative Process (DP)

Nancy

Nancy B. Beck, Ph.D., DABT
Deputy Assistant Administrator
Office of Chemical Safety and Pollution Prevention
P: 202-564-1273

Ex. 6 Personal Phone

beck.nancy@epa.gov

From: Lynn L. Bergeson [mailto:lbergeson@lawbc.com]

Sent: Monday, June 25, 2018 10:44 AM

To: 'Kramer, Claire' <ckramer@bloombergnext.com>; michael.gould@rahn-group.com; mbogle@vertellus.com; Beck,

Nancy <Beck.Nancy@epa.gov>

Cc: Heidi Brown Lewis <hlewis@lawbc.com>

Subject: RE: 11 AM ET webinar

Will do -logging in now

LYNN L. BERGESON
MANAGING PARTNER
BERGESON & CAMPBELL PC

2200 Pennsylvania Avenue, N.W. Suite 100W | Washington, D.C. 20037 T: 202-557-3801 | F: 202-557-3836 | M: 202-257-2872 | lawbc.com

From: Kramer, Claire [mailto:ckramer@bloombergnext.com]

Sent: Monday, June 25, 2018 10:40 AM

To: michael.gould@rahn-group.com; mbogle@vertellus.com; beck.nancy@epa.gov; Lynn L. Bergeson

Cc: Heidi Brown Lewis Subject: 11 AM ET webinar

Good Morning Everyone,

I look forward to working with you on today's webinar. Please let me know if you have any questions as you are dialing in and logging in.

Thank you! Claire

Claire Kramer Continuing Education/LMS Assistant

Bloomberg Next

Direct 703.341.5765 ckramer@bloombergnext.com

To unsubscribe or manage your email preferences, please <u>Click Here</u> © 2018 The Bureau of National Affairs, Inc. All rights reserved. 1801 South Bell Street, Arlington, VA 22202. Phone: 1.800.372.1033

Appointment

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/3/2020 12:21:39 AM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

Location: Ex. 6 Personal Privacy (PP) - conference code/call in number

Start: 10/8/2020 6:30:00 PM **End**: 10/8/2020 7:30:00 PM

Show Time As: Tentative

Recurrence: (none)

----Original Appointment----

From: Franz, Christina

Sent: Thursday, October 1, 2020 12:58 PM **To:** Franz, Christina; TSCA Section 5 Group

Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon

Gerber; Kerry Coy; Elizer, Emily B **Subject:** TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Formal agend to follow in the next few days.

Appointment

Franz, Christina [Christina_Franz@americanchemistry.com] From:

10/6/2020 5:25:44 PM Sent:

To: Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

Attachments: ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf

Ex. 6 Personal Privacy (PP) - conference code/call in number Location:

Start: 10/8/2020 6:30:00 PM End: 10/8/2020 7:30:00 PM

Show Time As: Tentative

Recurrence: (none)

From: Franz, Christina

Sent: Thursday, October 01, 2020 12:58 PM

Required: TSCA Section 5 Group

Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie Mcmichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna);

Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne

Subject: TSCA Section 5 EPA Meeting

When: Thursday, October 08, 2020 2:30 PM-3:30 PM. Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

To join via webex: Ex. 6 Personal Privacy (PP) - conference code/call in number

only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

TSCA Section 5 Work Group Meeting

	AGENDA	
Ex. 6 Personal Privacy (PP) - conference code/call in number	Access code	Ex. 6 Personal Privacy (PP) - conference code/call in number

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)
[HYPERLINK Ex. 6 Personal Privacy (PP) - conference code/call in number

Time	Торіс
2:30 p.m.	Welcome and Introductions
	 OCSPP Reorganization Safety Data Sheet Requirements on section 5 submissions Access to engineering and health assessment reports EPA's selection of analogues 2020 EPA Stakeholder Meeting on Section 5 40 CFR 720 revisions
3:25 p.m.	Next Steps
3:30 p.m.	Adjourn

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings. The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Councilsponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

 protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

Revised 3/80 (single page version) Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.;
 and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

 rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Appointment

Franz, Christina [Christina_Franz@americanchemistry.com] From:

10/3/2020 12:23:44 AM Sent:

To: Franz, Christina [Christina Franz@americanchemistry.com]; Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf Attachments:

Location: Ex. 6 Personal Privacy (PP) - conference code/call in number

Start: 10/8/2020 6:30:00 PM End: 10/8/2020 7:30:00 PM

Show Time As: Busy

Recurrence: (none)

From: Franz, Christina

Sent: Thursday, October 01, 2020 12:58 PM

Required: TSCA Section 5 Group

Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie Mcmichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna);

Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne

Subject: TSCA Section 5 EPA Meeting

When: Thursday, October 08, 2020 2:30 PM-3:30 PM. Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

To join via webex: Ex. 6 Personal Privacy (PP) - conference code/call in number

only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

TSCA Section 5 Work Group Meeting AGENDA

	AULIUA	
Ex. 6 Personal Privacy (PP) - conference code/call in number	Access code	Ex. 6 Personal Privacy (PP) - conference code/call in number

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)
[HYPERLINK | Ex. 6 Personal Privacy (PP) - conference code/call in number

Time	Торіс
2:30 p.m.	Welcome and Introductions
	 TSCA Discussion with EPA OCSPP Reorganization Safety Data Sheet Requirements on section 5 submissions Access to engineering and health assessment reports EPA's selection of analogues 2020 EPA Stakeholder Meeting on Section 5 40 CFR 720 revisions
3:25 p.m.	Next Steps
3:30 p.m.	Adjourn

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings. The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Councilsponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

 protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

Revised 3/80 (single page version) Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.;
 and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

 rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Appointment

From: Dekleva, Lynn [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3BB17AF28654434EB3C114BFCA797997-DEKLEVA, LY]

Sent: 10/6/2020 6:33:22 PM

To: Franz, Christina [Christina_Franz@americanchemistry.com]

Subject: Accepted: FW: TSCA Section 5 EPA Meeting

Location: Ex. 6 Conference Code

Start: 10/8/2020 6:30:00 PM **End**: 10/8/2020 7:30:00 PM

Show Time As: Busy

Appointment

Franz, Christina [Christina_Franz@americanchemistry.com] From:

10/3/2020 12:23:44 AM Sent:

To: Franz, Christina [Christina Franz@americanchemistry.com]; Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

Attachments: ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf

Location: Ex. 6 Personal Privacy (PP) - conference code/call in number

Start: 10/8/2020 6:30:00 PM End: 10/8/2020 7:30:00 PM

Show Time As: Tentative

Recurrence: (none)

From: Franz, Christina

Sent: Thursday, October 01, 2020 12:58 PM

Required: TSCA Section 5 Group

Optional: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Shelp, Catherine; Mavian, Kari; Hoff, MaryAnn; 'Muellner, Mark'; Willard, Travis; Bechtold, Nicole; Hunley, Jackie; Roesh, Denise M.; Levinson, Marcia; McMichael, Carrie; Domush, Hilary I.; Clark, Emily; Podolak, Sandra; Skulsky, Joseph; Shade, William; Keller, Laura H.; Grove, Scott L.; Gerber, Jonathan; Coy, Kerry; Elizer, Emily; Dekleva.lynn@Epa.gov; 'Braun, Robert'; 'Catherine J Shelp'; 'Mavian, Kari (K)'; 'Hoff, Mary Ann'; 'Willard, Travis L'; 'Nicole Bechtold'; 'Hunley, Jackie R'; 'Roesh, Denise M'; 'Marcia Levinson'; 'Carrie Mcmichael'; 'DOMUSH, HILARY L'; 'Clark, Emily'; 'Sandra Podolak'; 'Joseph Skulsky'; 'William Shade'; 'Keller, Laura H'; 'Grove, Scott Lee'; 'Jon Gerber'; 'Kerry Coy'; 'Elizer, Emily B'; Gale, Kat; Osman-Sypher, Sahar; Hillebold, D. (Donna); Nikitenko, Antonia; Hayes, Mike; Kennedy, Wayne

Subject: TSCA Section 5 EPA Meeting

When: Thursday, October 08, 2020 2:30 PM-3:30 PM. Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

Ex. 6 Personal Privacy (PP) - conference code/call in number To join via webex:

only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

TSCA Section 5 Work Group Meeting

	AGENDA	
i		
Ex. 6 Personal Privacy (PP) - conference code/call in number	Access code	Ex. 6 Personal Privacy (PP) - conference code/call in number

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)
[HYPERLINK | Ex. 6 Personal Privacy (PP) - conference code/call in number

Time	Торіс
2:30 p.m.	Welcome and Introductions
	 TSCA Discussion with EPA OCSPP Reorganization Safety Data Sheet Requirements on section 5 submissions Access to engineering and health assessment reports EPA's selection of analogues 2020 EPA Stakeholder Meeting on Section 5 40 CFR 720 revisions
3:25 p.m.	Next Steps
3:30 p.m.	Adjourn

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings. The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Councilsponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

 protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

Revised 3/80 (single page version) Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.;
 and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

 rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/3/2020 12:23:44 AM

To: Franz, Christina [Christina Franz@americanchemistry.com]; TSCA Section 5 Group

[TSCASection5Group@americanchemistry.com]

CC: Hartigan, Suzanne [Suzanne_Hartigan@americanchemistry.com]; Howard, Brett

[Brett_Howard@americanchemistry.com]; Braun, Robert [Robert.Braun@Lubrizol.com]; Shelp, Catherine [catherine.shelp@basf.com]; Mavian, Kari [kmavian@dow.com]; Hoff, MaryAnn [hoff@ppg.com]; 'Muellner, Mark'

[mmuellner@ecolab.com]; Willard, Travis [tlwill@ascendmaterials.com]; Bechtold, Nicole [ntbechtold@mmm.com]; Hunley, Jackie [jackie.r.hunley@exxonmobil.com]; Roesh, Denise M. [Denise.Roesh@Chevron.com]; Levinson, Marcia [marcia.levinson@covestro.com]; McMichael, Carrie [carrie.mcmichael@solvay.com]; Domush, Hilary I. [hilary.l.domush@dupont.com]; Clark, Emily [eclark@eastman.com]; Podolak, Sandra [sandra.podolak@solvay.com]; Skulsky, Joseph [JSkulsky@stepan.com]; Shade, William.Shade@fmc.com]; laura.h.keller@exxonmobil.com;

Grove, Scott L. [scott.l.grove@dupont.com]; Gerber, Jonathan [jmgerber1@mmm.com]; Coy, Kerry [kerry.coy@basf.com]; Elizer, Emily [eelizer@ppg.com]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Gale, Kat

[Kat_Gale@americanchemistry.com]; Sahar_Osman-Sypher@americanchemistry.com

Subject: TSCA Section 5 EPA Meeting

Attachments: ACC Section 5 Work Group Meeting 10 08 20.docx; Doc 1 Anti Trust Checklist.pdf

Location:

Ex. 6 Conference Code

Start: 10/8/2020 6:30:00 PM **End**: 10/8/2020 7:30:00 PM

Show Time As: Tentative

Recurrence: (none)

When: Thursday, October 08, 2020 2:30 PM-3:30 PM. (UTC-05:00) Eastern Time

(US & Canada)

Ex. 6 Conference Code

~~*~*~*~*~*

Agenda and Antitrust Checklist attached. We have a full agenda for the one hour meeting, but if you have any other suggested topics to discuss, please forward them to me as soon as possible. Thank you.

To join via webex: https://americanchemistry.webex.com/meet/christina_franz

TSCA Section 5 Work Group Meeting AGENDA

Ex. 6 Conference Code

October 8, 2020 | 2:30 a.m.—3:30 p.m. (Eastern)

[HYPERLINK "https://americanchemistry.webex.com/meet/christina_franz"]

Time	Торіс
2:30 p.m.	Welcome and Introductions
	TSCA Discussion with EPA
	 OCSPP Reorganization Safety Data Sheet Requirements on section 5 submissions Access to engineering and health assessment reports EPA's selection of analogues 2020 EPA Stakeholder Meeting on Section 5 40 CFR 720 revisions
3:25 p.m.	Next Steps
3:30 p.m.	Adjourn

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings. The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Councilsponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

 protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

Revised 3/80 (single page version) Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.;
 and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

 rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Appointment

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/3/2020 12:23:44 AM

To: Franz, Christina [Christina Franz@americanchemistry.com]; Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: FW: TSCA Section 5 EPA Meeting

Location: Ex. 6 Personal Privacy (PP) - conference code/call in number

Start: 10/8/2020 6:30:00 PM **End**: 10/8/2020 7:30:00 PM

Show Time As: Tentative

Recurrence: (none)

----Original Appointment----

From: Franz, Christina

Sent: Thursday, October 1, 2020 12:58 PM **To:** Franz, Christina; TSCA Section 5 Group

Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon

Gerber; Kerry Coy; Elizer, Emily B **Subject:** TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Formal agend to follow in the next few days.

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

Message

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 12/9/2020 7:07:39 PM

To: Passe, Loraine [Passe.Loraine@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; master.barbara@epa.gov;

Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Master, Barbora [Master.Barbora@epa.gov]

Subject: RE: 40 CFR 720 question

Attachments: ACC Preliminary Comments PMN Regulations NPRM 12 09 2020 Final.pdf

Dear Loraine,

Thank you so much for following up with me on my question. I will be sure to communicate this to our membership.

In addition, I have attached for your consideration ACC's Preliminary Comments on the NPRM on PMN Procedures EPA is currently developing. Thank you again for the opportunity to contribute to the process and we will look forward to continuing to work with you as these move forward. Please let me know if you have any questions on these comments.

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o) 301-580-6562 (c)

From: Passe, Loraine [Passe.Loraine@epa.gov]

Sent: Monday, December 07, 2020 9:08 AM

To: Franz, Christina; Dekleva, Lynn; master.barbara@epa.gov; Fehrenbacher, Cathy; Master, Barbora

Subject: RE: 40 CFR 720 question

Hi Christina-

Ex. 5 Deliberative Process (DP)

Thanks again,

Loraine

Loraine Passe, Chief
Risk Management Branch 1
New Chemicals Division
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Phone: (202) 564-9064

From: Franz, Christina < Christina _ Franz@americanchemistry.com>

Sent: Thursday, December 3, 2020 11:37 AM

To: Passe, Loraine <Passe.Loraine@epa.gov>; Dekleva, Lynn <dekleva.lynn@epa.gov>; master.barbara@epa.gov;

Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Master, Barbora <Master.Barbora@epa.gov>

Subject: RE: 40 CFR 720 question

Ex. 5 Deliberative Process (DP)

Thank you very much,

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o) 301-580-6562 (c)

Christina Franz@americanchemistry.com

From: Passe, Loraine [Passe.Loraine@epa.gov] **Sent:** Monday, November 23, 2020 1:06 PM

To: Franz, Christina; Dekleva, Lynn; master.barbara@epa.gov; Fehrenbacher, Cathy; Master, Barbora

Subject: RE: 40 CFR 720 question

Hi Christina-

Ex. 5 Deliberative Process (DP)

Loraine Passe, Chief Risk Management Branch 1 New Chemicals Division

Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency

Phone: (202) 564-9064

From: Franz, Christina < Christina _Franz@americanchemistry.com>

Sent: Monday, November 23, 2020 9:19 AM

To: Dekleva, Lynn < dekleva.lynn@epa.gov>; Passe, Loraine < Passe.Loraine@epa.gov>; master.barbara@epa.gov;

Fehrenbacher, Cathy <Fehrenbacher.Cathy@epa.gov>; Master, Barbora <Master.Barbora@epa.gov>

Subject: 40 CFR 720 question

Hello ladies,

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o) 301-580-6562 (c)

Christina_Franz@americanchemistry.com

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.



December 9, 2020

Ms. Loraine Passe Mail Code: 7405M Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460

Re: EPA Modifications to New Chemical Regulations at 40 CFR 720

Dear Loraine:

Thank you for your interest and solicitation of ACC's preliminary suggestions and early input on EPA's Notice of Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics (OPPT). As we understand the goals of the upcoming NPRM, they are to:

- o Align the current regulations with the 2016 Lautenberg amendments
- o Clarify regulatory requirements
- o Improve the premanufacture notice (PMN) process so that its more predictable, transparent, and efficient

EPA has identified its general interest in how efficiencies might be gained overall in the PMN process, and specifically, how those efficiencies might be achieved by reducing or mitigating the frequency of PMN amendments occurring due to "excessive rework of cases" and "late information" submissions.¹

A. Reducing Frequency of Amendments and Late Information Submissions

EPA and ACC agree that frequent amendments and multiple information submissions contribute to delays. We have identified below a number of recommendations that we believe may reduce the delays associated with amendments and revised submissions.

1. Streamline EPA Reviews

The PMN process could be improved if EPA were to adopt a more comprehensive and streamlined chemical review/assessment of PMNs. Since EPA appears to divide a PMN into disparate sections for review, e.g., hazard information reviewed distinct from exposure, chemical reviewers and risk assessors are not accounting for the entirety of the submission when evaluating a PMN. Submitters believe that this bifurcated review unnecessarily may lead to misunderstandings or misimpressions regarding the submission, resulting in frequent delays, unnecessary discussions between Project Managers (PMs) and submitters, and inaccurate outputs in the health, fate, engineering reports, etc. This bifurcated review process at EPA is one clear source of delays and confusion.



¹ EPA's November 2020 one-page Summary of the NPRM for Stakeholder Outreach document.

2. Ensure Transparent Consideration of All Information Submitted with Documentation of Decision Making

ACC members report that EPA often misses or ignores analytical and/or toxicological information in lieu of models, and does not give appropriate weight to the processing and use information submitted. The TSCA amendments require EPA to consider all available information and use the best available information as well as a weight of the evidence approach. In addition, these unnoticed or disregarded key pieces of information would often mitigate or alleviate EPA's identified concerns. ACC believes it is reasonable to expect EPA to be more explicit in its new chemical reviews to explain how, when, where and why it has used and evaluated the information submitted as well as its rationale for using more conservative modeled data in lieu of actual data.

We have provided the following examples to illustrate ACC concerns.

- Example A: A company submitted an LVE for a liquid substance with a very low vapor pressure. The program manager indicated the EPA evaluated the LVE as a solid substance and had inhalation concerns. After further communication, EPA recognized the LVE filing indicated it was liquid substance multiple times and provided data for low-vapor pressure that was not used by the engineer in their reports.
- Example B: A company submitted an acute fish toxicity study (OECD Test Method) to support a PMN submission. While the EPA did not ignore the test report, it did not accept the (favorable) results and instead defaulted to models.
- Example C: A company submitted a dossier for a material stating and binding to "no exposure." However, EPA did not accept the explanation provided within the dossier or the binding agreement to zero exposures, and proceeded with an inhalation hazard exposure risk assessment.

3. Communicate with Submitters at Start of the Assessment to Align Parties

EPA should communicate with submitters at the earliest stages of the review that will comprise the engineering report to discuss and determine the appropriate use of submitted data, structure activity results, and read-across data. Doing so would provide a method by which to align the submitter and agency at the beginning of the process, enabling earlier negotiations that should, more often than not, result in a more robust and aligned risk assessment output(s). It should also help reduce EPA's "rework" or "late information" submission concerns because both parties would/should have a consistent understanding at the outset rather than continuing the current approach that does not apprise the submitter of issues/concerns until EPA has completed the review that will comprise the engineering report. The current approach leads to re-starts, amendments, etc.

4. Identify Actions that Do and Do Not Suspend or Amend the 90-Day Statutory Review Period

The extent to which communications between a PMN submitter and EPA result in a suspension of amendment of the PMN that restarts or resets the 90-day timeline is often problematic. EPA should establish criteria or identify specific actions that will and will not constitute a basis for a suspension or amendment in order to provide greater consistency and clarity for submitters. Otherwise, the impact of lengthy delays in EPA's review may, in fact, be thwarting



congressional intent that new chemical reviews be processed within a reasonable three-month period, consistent with promoting economic innovation.²

ACC members indicate that EPA often seeks more information when the 90-day review period is nearly expired. It is unclear whether this is a temporary situation due to a backlog or some other transitory reason or whether this is something more systemic. Companies believe that EPA should contact submitters immediately after the "focus meeting" or EPA moves to "Preparation of Recommendations" (Day 21 – 85) as the EPA PMN Process diagram describes. ACC believes that EPA adhering to its own process timeline could result in shorter review periods as it would allow businesses to address concerns identified by the EPA before the initial Day 90; potentially eliminating the need for a suspension request.

EPA might also consider allowing submitters an alternate approach to a suspension, which does not contribute to the running of the 90-day clock, e.g., a "hold" that permitted submitters to conduct a new study within a set timeframe to address potentially unforeseen concerns without having to resubmit a new PMN and pay an additional fee. This alternative could be helpful where EPA identifies conditions not reasonably anticipated by the submitter.

ACC believes that certain actions or circumstances should not be deemed a PMN amendment:

- uploading of a signed copy of a consent order to a PMN
- uploading a compliance plan required by a consent order or proposed modifications or revisions to a proposed compliance plan (e.g., up to a predetermined number or timeframe)

In addition, we believe that certain circumstances resulting in delays are attributable to EPA and should not operate so as to penalize the submitter, e.g., EPA ignoring or failing to identify relevant information provided by the submitter. EPA should acknowledge accountability for these circumstances, and adopt transparent internal protocols to prevent or mitigate against them.

5. Implement Procedures that Demonstrate Utilizing the Pre-Consultation Meeting (PCM) Process Improves the New Chemical Process and Timeline

ACC members report that scheduling PCMs is often difficult, at times taking as long as three months or more to arrange. In such cases, companies believe it would make more sense to simply submit the PMN and skip the PCM altogether. In addition, company representatives have been told by EPA program managers that they were being encouraged by others at EPA not to schedule PCMs due to resource constraints, and to instead answer questions over the phone. Companies are discouraged by the fact that PCMs have been touted by the agency as a way to expedite the PMN process, while their actual experiences have not borne out this purported benefit—with some ACC members reporting that requesting a PCM will actually slow the process down.

americanchemistry.com®

Ŵ

² At least one company reports that 15-day suspensions in one PMN have resulted in a two-year delay.

6. Establish Criteria and Define What Constitutes "Reasonably Foreseen" Consistent with TSCA's Risk-Based Scientific Standards

Companies report that EPA frequently raises concerns or establishes requirements regarding uses that were not included in the PMN. ACC recognizes "reasonably foreseen" uses are within the scope of EPA's review; however, EPA often identifies potential uses that arguably are not reasonably probable or even possible for certain chemistries. These circumstances can be particularly challenging to address, e.g., proving a negative or establishing evidence of absence, which may not be feasible to demonstrate.

Companies indicate that EPA is not clear what distinguishes unreasonable from reasonable in the context of the new chemicals program. For example, in the context of nearly every home-care product EPA assumes that a spray application is foreseeable, even when the substance is a solid. In particular, unit-dose product tablets frequently are characterized as a "foreseen use," though it is not apparent why anyone would dissolve solid tablets, put them in bottles, and spray the solution. Developing responses to EPA's perceived unusual and unrealistic uses consumes considerable time—especially when EPA does not articulate the source or basis upon which it has identified the theoretical use and potential applications—let alone the time expended trying to refute or prove the negative.

Two other examples below offer additional illustrations of exchanges with submitters that contribute to unnecessary delays:

- Example D: EPA made assumptions that low-MW fragments must exist based on a reactant composition despite data demonstrating that the low-MW do NOT exist at the levels EPA claimed. EPA's persistent assumption in the face of contrary data appears to suggest an unwillingness to find no unreasonable risk.
- Example E: EPA and a company went back and forth regarding a substance where isocyanate functionality was completely blocked, a characteristic substantiated by CAS by adding the word "blocked" in the chemical name and in the reactant composition. This demonstration had been sufficient information previously, even after the TSCA amendments were enacted. However, an EPA toxicologist insisted that small amounts of free isocyanate could still exist and we had to do one more test (an IR spectra) to show, once again, there was no free isocyanate functionality.³

EPA has not, to our knowledge, defined how it interprets the term "reasonably foreseen" in the new chemicals program. The only indication of EPA's interpretation of the term of which we are aware is set forth in the TSCA Risk Evaluation rule, which states:

The Agency is committed to exercising its discretion to determine the conditions of use in a reasonable manner and will not base this determination upon

³Companies report inconsistencies among reviewers' requirements and evaluations regarding identical chemistries. For example, one reviewer will identify a concern regarding site disposal or a potential human health exposure concerns during manufacturing, but another will not comment on these or raise any concern at all.



hypotheticals or conjecture. The identification of "reasonably foreseen" conditions of use will necessarily be a case by case [sic] determination, and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical's properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable.⁴

EPA is now four years into implementation of amended TSCA and should have sufficient experience (atop the decades of experience derived implementing original TSCA) to articulate what constitutes a "reasonably foreseen" condition of use. EPA should, at this stage, be able provide more clarity regarding the criteria or factors it utilizes to determine what constitutes "reasonably foreseen."

7. Improve Intra-Agency Coordination and Understanding

ACC member companies report that their experience in the new chemicals program leads them to believe that EPA staff would benefit from a greater understanding and awareness of the other environmental statutes and regulatory programs in place that work in tandem to establish the federal environmental framework. ACC believes that Administrator Wheeler's September 2020 directive that OCSPP work with various program offices in EPA to establish a TSCA Coordinating Committee to coordinate actions under TSCA, provides a solid basis upon which to implement such an effort. Improved understanding and coordination of the existing regulatory requirements under other statutes could lead to expedited new chemical reviews.

8. Establish Criteria for Analog Selection

EPA's criteria or factors considered when identifying and selecting PMN substance analogs lacks transparency. Frequently, submitters complain that the analogs used by the agency when evaluating new chemical submissions are inappropriate. In addition, the agency often ignores or fails to use the analogs identified by the submitter in the PMN, without explanation. ACC recommends that EPA identify criteria by which an analog will be deemed appropriate for selection when reviewing new chemical submissions, and that EPA specifically address and explain why it did not use the submitter's recommended analog.

9. EPA Should Update its Generic Exposure Scenarios

ACC believes many of EPA's generic exposure scenarios used are out-of-date, leading to unrealistically conservative assumptions. EPA project managers have acknowledged that the processing information utilized is frequently at least 20 years old. EPA must update outdated tools and information sources in order to evaluate new chemical submissions realistically and accurately—in line with current industry practices.

_



⁴ 82 Fed. Reg. 33726, 3370-33731 (July 20, 2017).

B. Other Improvements and Efficiencies that Should be Implemented

1. Many New Chemical Reviews Should Include A Mid-Review Collaborative Discussion Session

ACC believes many new chemical submissions, as well as EPA staff and industry submitters, would benefit greatly from live or virtual real-time interactions with one another at strategically timed intervals during the new chemical review. These scheduled discussions should include the key risk assessment staff responsible for the technical aspects of the review to enable comprehensive and robust engagement of the scientific and technical issues presented by the new chemical submission. These should not be sessions where the Program Manager is substituted in an effort to translate issues or concerns identified by the EPA risk assessment team. ACC has at times participated in such sessions that have been arranged in circumstances where industry and EPA appeared to be at an impasse in communications regarding a submission.

2. Reinvigorate the Sustainable Futures Programs and Institute EPA/Industry Mutual Training Sessions

Industry (and likely EPA as well) benefitted substantially from the implementation of the Sustainable Futures Program, which trained chemical developers on the same risk-screening models that EPA uses to evaluate new chemicals before they enter the market. The goal of Sustainable Futures was to provide these computer-based models and training in their use to help companies develop safer chemicals quickly and cost-effectively. Companies that take the training and graduate from Sustainable Futures became eligible for an expedited EPA premanufacture review.

In turn, many new chemical submitters believe EPA staff would benefit from improved training regarding how U.S. chemical businesses function, and how and why chemistries are not automatically interchangeable. ACC would welcome opportunities to develop mutually beneficial training and educational opportunities with EPA.

3. Replace or Upgrade the Central Data Exchange System

The Central Data Exchange (CDX) requires a significant upgrade across EPA's TSCA program. The system crashes frequently, is difficult to navigate, and often fails to provide submitters with appropriate validations and overall confidence that their submissions are complete, accurate, and an otherwise precise rendition of what was provided by the company.

4. Revise the New Chemical Submission Forms

ACC will seek to provide more robust comment on this recommendation in the future, e.g., in response to EPA's NPRM proposal. We believe that there are improvements to the PMN submission form that can be made to indicate more clearly and specifically the type of information and details that submitters can provide to maximize the likelihood of a successful submission. Improvements to the form would be particularly helpful to newer submitters who do not have the benefit of more robust experience with the program.

5. EPA Should Revise its Policies and Regulations Regarding Health and Safety Studies to Reflect its Broader Authority Under TSCA



Over the past decade, ACC has prepared and submitted to EPA several White Papers and analyses regarding EPA's unduly narrow and misplaced interpretation of its authority under TSCA section 14. ACC has attached several of these documents as Appendix A. Briefly, the papers demonstrate that EPA has discretion under section 14 to disclose the study reports for studies submitted under TSCA and to withhold from public disclosure the data underlying of those study reports that are submitted to EPA or which EPA otherwise obtains.

EPA possesses the authority to and should balance the competing interests of public access to health and safety studies submitted under TSCA and protection of data compensation rights of the study submitters. EPA may do this under section 14 of TSCA by accepting substantiated claims that underlying data qualify for protection from disclosure under section 14(a). Disclosing the final study report while withholding the underlying data would provide the public with key information about the study while protecting the rights of data owners.

It is puzzling why EPA would persist in interpreting language that, on its face, grants the agency discretion as language that prohibits the very discretion it actually grants, but persist it does. We strongly encourage EPA to revisit its interpretation of section 14 and revise PMN regulations accordingly—enabling EPA to exercise the discretion it possesses in the context of CBI contained within health and safety studies.

6. Adverse Impact of SNURs Should be Mitigated

EPA continues to apply SNURs to new chemicals that have received a "not likely to present an unreasonable risk...for intended and reasonable foreseen uses." ACC is concerned that the regulatory burden associated with a SNUR substance, regardless of the conditions, and that the SNUR in fact does apply to the PMN submitter. This results in disproportionate restrictions to new chemicals while substantially similar materials are already being used safely without a SNUR. In effect, EPA is restricting the use of newly developed materials that are often designed to be more sustainable and environmentally responsible than existing materials.

7. Test Recommendations in Pilot Program

ACC recommends that EPA and ACC consider a collaboration during 2021 during which EPA pilot and test whether any of the recommendations outlined above that EPA may be reticent to implement, e.g., the "Mid-Review Collaborative Discussion Session" discussed below in B.1., would improve the efficiency of the new chemicals program. The pilot program could test recommended approaches on a sampling of new chemical submissions and evaluate whether and to what extent the tested approaches improved the efficiency of the program. We would welcome further discussions to explore the potential for implementing such a pilot program.

ACC appreciates the opportunity to provide these preliminary recommendations regarding EPA's anticipated NPRM on the new chemicals program procedures. Please let me know if you have any questions.

Sincerely,
Christina Inanz

Christina Franz



Attachment - A



White Paper

TSCA Protects Confidential Chemical Identities in Health and Safety Studies From Disclosure

Of Counsel: Mark N. Duvall Beveridge & Diamond, P.C. 1350 I Street, N.W. Washington, DC 20005 (202) 789-6090 mduvall@bdlaw.com Christina Franz
Senior Director, Regulatory & Technical Affairs
American Chemistry Council
700 Second Street, N.E.
Washington, DC 20002
(202) 249-6406
christina franz@americanchemistry.com

February 21, 2012

Table of Contents

		<u>Pag</u> e	<u>ə</u>	
EXE	CUTIVE	SUMMARY	1	
DISC	USSIO	N	4	
I.	Policy	Reasons Why EPA Should Reconsider Its Interpretation of Section 14	4	
Π.	Backg	ground on Section 14	7	
III.	The Text of TSCA Shows Intent to Protect Trade Secret or Confidential Chemical Identities in Submitted Health and Safety Studies			
	A.	Section 14(a) Protects Trade Secret or Confidential Commercial Information in or Underlying Studies	8	
	B.	Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 5	0	
	C.	Protection of Trade Secret or Confidential Chemical Identities in Studies Submitted Under Section 4	2	
	D.	Section 8(a) Illustrates How Section 14 Protects Chemical Identities	3	
	E.	Protection of Trade Secret or Confidential Chemical Identities in Studies Where Disclosure Would Reveal Process Information	3	
	F.	Protection of Trade Secret or Confidential Chemical Identities in Studies on R&D Chemicals and Mixtures	3	
	G.	Implications for Other Studies Submitted Under TSCA	4	
IV.	Trade	egislative History Demonstrates That Congress Wanted EPA to Protect Secret or Confidential Chemical Identities When Disclosing Health and Studies	5	
	A.	1972 FIFRA Amendments	5	
	B.	Debate About Disclosure of Health and Safety Studies Under FIFRA10	6	
	C.	Congressional Consideration of TSCA in 1975-1976	8	
		Stakeholder Comments on Disclosure of Health and Safety Studies	8	

		2. The 1976 Provision on Disclosure of Health and Safety Studies	20	
V.	Enviro	as Part of a Series of Statutes Mandating Disclosure of Health and commental Information on Chemicals but Not Confidential Chemical ties	22	
	A.	Federal Environmental Pesticide Control Act of 1972	23	
	B.	Federal Pesticide Act of 1978	23	
	C.	Comprehensive Environmental Responses, Compensation, and Liability Act of 1980	24	
	D.	Emergency Planning and Community Right-to-Know Act of 1986	24	
	E.	Superfund Amendments and Reauthorization Act of 1986, Title I	25	
	F.	Implications for TSCA	26	
VI.		Recognition of Its Need to Balance Disclosure of Health and Safety Studies Protection of Trade Secret or Confidential Chemical Identities	26	
VII.	Steps EPA Should Take to Protect Confidential Chemical Identities			
	A.	EPA Should Revise Its Regulations and Guidance to Allow Confidentiality Claims for Confidential Chemical Identities in Studies Where Appropriate	28	
	B.	EPA Should Consider Requiring Generic Names and Substantiation for Trade Secret or Confidential Chemical Identities in Health and Safety Studies_and Requiring Up-Front Substantiation of CBI Claims for Studies	29	
	C.	EPA Should Work With Industry and NGOs to Improve Development of Generic Names	31	
	D.	EPA Should Allow CBI Claims for Chemical Identities in Studies Where Appropriate	32	
	E.	EPA Should Allow CBI Claims for Chemical Identities in R&D Mixtures Where Appropriate.	32	
CON	CLUSIC)N	33	

EXECUTIVE SUMMARY

Citing section 14(b) of the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) has recently called for the disclosure of chemical identities in health and safety studies submitted under TSCA, notwithstanding objections by the study submitters that the chemical identities are trade secrets or confidential commercial information. EPA has developed a policy against confidential business information (CBI) protection for chemical identities in or underlying such studies. EPA should reconsider that CBI disclosure policy for both policy and legal reasons, and take specific steps to protect confidential chemical identities where appropriate. Under TSCA, EPA must balance the interest in disclosure against the interest in protecting trade secret and confidential chemical identities. It may do so by protecting that information while also providing the public with the information it needs to evaluate those studies, such as through a requirement for structurally-descriptive generic names.

There are strong policy reasons why EPA should reconsider its stance against CBI protection for chemical identities in health and safety studies. Trade secrets are crucial to U.S. leadership in innovation in a global economy, but the CBI disclosure policy may erode that leadership by reducing the protection for trade secrets. In the chemical industry, trade secret chemical identities are among the most valuable intellectual property, yet they often cannot be patented. The composition of formulations can be particularly valuable, especially for small businesses. Under the CBI disclosure policy, EPA would reveal those chemical identities when they are the subject of a health and safety study submitted under TSCA, notwithstanding CBI claims. This may have the effect of discouraging innovation and the jobs and greener chemicals that result from innovation, and driving jobs outside the U.S.

The CBI disclosure policy reflects EPA's legal perspective that section 14(b) requires disclosure of trade secret or confidential chemical identities in most studies submitted under TSCA. That perspective is flawed. The CBI disclosure policy runs counter to the text and legislative history of TSCA, as well to nearly 30 years of EPA policy and regulation. This paper establishes that in section 14 and the rest of TSCA, Congress intended for EPA to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA, while also providing the public with the information it needs to evaluate those studies.

The Congressional intention to protect trade secret or confidential chemical identities is reflected in the text of TSCA itself. Read as a whole, TSCA shows consistent concern for the protection of chemical identities that are trade secrets or confidential commercial information:

- Section 14(a) provides broad protection for trade secret or confidential commercial information. Section 14(b) cuts back on that protection for health and safety studies, but it requires health and environmental information, such as effects information, to be available for disclosure, not trade secret or confidential commercial information in those studies. Section 14(a) protects any trade secret or confidential commercial information in those studies other than health and environmental information.
- Both sections 5(b)(3) and 5(d)(2) mandate public disclosure of data from health and safety studies submitted under section 5, subject to protection for trade secret or

confidential chemical identities and other information in those studies under section 14. Section 5(d)(2) specifically endorses disclosure of generic names instead of confidential identities except where "required in the public interest."

- Section 4(d) similarly mandates public disclosure of data from health and safety studies submitted under section 4, subject to protection for trade secret or confidential chemical identities and other trade secret information in those studies under section 14.
- Section 8(a) authorizes EPA to require reporting of chemical identities and other information which is typically confidential without even mentioning section 14, indicating an expectation that section 14(a) protects such information when it is trade secret or confidential.
- Section 14(b) excludes trade secret or confidential chemical identities that, if disclosed, would result in disclosure of process information.
- Section 14(b) also excludes studies on R&D chemicals, for which the public interest in disclosure of trade secret or confidential commercial information is generally limited and the competitive interest in non-disclosure of such information is generally high.

This intention to protect trade secret or confidential chemical identities while disclosing health and safety studies is also manifest in the legislative history of TSCA. While considering TSCA, Congress recognized that its 1972 amendments to the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA), which also required the disclosure of health and safety studies, had raised a question of whether a study could be claimed as a whole to be a trade secret or confidential commercial information and thereby be protected from disclosure. EPA took the position that studies as a whole are not trade secrets or confidential commercial information.

With section 14(b), Congress intended to incorporate that position in TSCA. However, in the FIFRA debate, EPA carefully differentiated between studies as whole and chemical identities in or underlying those studies. EPA concluded that the trade secret or confidential identities in studies submitted under FIFRA are protected from disclosure. Stakeholders in the TSCA hearings similarly advocated for disclosure of studies, but recognized the need for continued protection of trade secret or confidential chemical identities. With section 14 of TSCA, Congress adopted EPA's viewpoint both that studies as a whole are not protected from disclosure, and that trade secret or confidential commercial information in or underlying them should be protected from disclosure.

TSCA is the second of six statutes enacted by Congress between 1972 and 1986 related to public disclosure of health and environmental information about chemicals. In all five of the other statutes, health and environmental information is required to be disclosed, but trade secret or confidential chemical identities are protected from disclosure. TSCA is not an exception, but rather should be recognized to be part of the same Congressional approach making health and environmental effects information public while protecting competitively sensitive information such as chemical identities.

EPA has long recognized that it has authority under section 14 to protect trade secret or confidential chemical identities in or underlying studies submitted under TSCA. In multiple rulemakings under section 5, it explicitly balanced the interest in disclosure of studies against the interest in protecting trade secret or confidential chemical identities in those studies by requiring disclosure except where disclosure is unnecessary to interpret the studies, such as by the provision of structurally-descriptive generic names. This longstanding legal interpretation by EPA is consistent with the text and legislative history of TSCA.

EPA should take several steps to balance transparency with protection of competitively sensitive information:

- Currently, EPA's regulations and guidance disallow confidentiality claims for chemical
 identities in or underlying studies, other than to a limited extent in its PMN and MCAN
 regulations. EPA should revise those regulations and guidance to allow such claims in
 appropriate circumstances. It should not proceed with its planned initiative to delete
 those provisions in its PMN and MCAN regulations.
- To address the need for public understanding of health and safety studies, EPA should consider requiring that structurally-descriptive generic names be provided in lieu of trade secret or confidential chemical identities for all studies submitted under TSCA. Generic names can provide important information to the public while still protecting competitively sensitive information important for innovation. EPA should also consider requiring up-front substantiation of CBI claims for chemical identities in studies.
- EPA should work with industry and NGOs to improve the process for determining
 appropriate generic names, both for the identities of chemical substances in studies and
 for names of PMN substances. The current process is unnecessarily resource-intensive.
 Industry representatives would volunteer to work with EPA and NGOs to streamline and
 otherwise improve the process.
- EPA should allow CBI claims for confidential identities of chemical substances in or underlying health and safety studies where appropriate. With structurally-descriptive generic names, an improved process for determining generic names, and an up-front substantiation requirement, the balance between transparency and protection of competitively sensitive information would be shifted to allow the disclosure of generic names rather than specific chemical identities where appropriate.
- EPA should not require disclosure of the components of R&D mixtures that are the subject of studies. Section 14(b) does not apply to mixtures which have not been offered for commercial distribution, such as R&D mixtures. Accordingly, EPA should protect confidential identities of components of R&D mixtures.

DISCUSSION

I. Policy Reasons Why EPA Should Reconsider Its Interpretation of Section 14

EPA has a policy of requiring disclosure of confidential chemical identities in or underlying health and safety studies submitted under TSCA. EPA should reconsider that CBI disclosure policy. It is based on a flawed interpretation of section 14 and may have serious adverse impacts on innovation and on small business. It may help drive chemical industry jobs overseas.

EPA must consider these impacts. In section 2(c) of TSCA, Congress expressed its intent that EPA "shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action" taken under TSCA. The CBI disclosure policy is neither reasonable nor prudent, and it may be having adverse economic and social impacts. Further, in section 2(b)(3), Congress found that "authority over chemical substances and mixtures should be exercised in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." The CBI disclosure policy is such an unnecessary economic barrier to innovation.

Trade secret protection is crucial to U.S. competitiveness. According to the National Science Foundation's National Science Board, intellectual property in the form of trade secrets is a critical factor as the United States competes in a global marketplace:

In most broad aspects of S&T [science and technology] activities, the United States continues to maintain a position of leadership but has experienced a gradual erosion of its position in many specific areas

The United States runs a surplus with the rest of the world in trade of intangible assets, including patent licensing fees and use of trade secrets An important component of the surplus in U.S. intangible assets is generated by industrial processes (\$19 billion), which include licensing fees for patents and use of trade secrets. U.S. exports in this category were \$37 billion in 2007.¹

The United States needs to protect its leadership in scientific and technological innovation. In the chemical industry, innovation often depends upon trade secret protection for trade secret or confidential chemical identities.

Trade secret protection also serves important public policy goals. As the Supreme Court has noted:

Trade secret law encourages the development and exploitation of those items of lesser or different invention than might be accorded protection under the patent laws, but which items still have an important part to play in the technological and scientific advancement

¹ National Science Board, Science and Engineering Indicators 2010 (2010), http://www.nsf.gov/statistics/seind10/pdfstart.htm, at O-3, 6-5.

of the Nation. Trade secret law promotes the sharing of knowledge, and the efficient operation of industry; it permits the individual inventor to reap the rewards of his labor by contracting with a company large enough to develop and exploit it. Congress, by its silence over these many years, has seen the wisdom of allowing the States to enforce trade secret protection. Until Congress takes affirmative action to the contrary, States should be free to grant protection to trade secrets.²

More particularly, confidential chemical identities in health and safety studies have recognized economic value, as a government report found:

Further, specific identification of a product in a health and safety study may inform competitors that a product has commercial value or that it is used in a particular manufacturing process. This concern is particularly applicable to catalysts and intermediates that may not be detectable in the commercial product.

Although the sensitivity of releasing confidential data is greatest at the beginning of a product's commercial life cycle, release of such data about an existing product may have some of the same economic consequences as disclosure of confidential data regarding a new product.³

The legislative history of TSCA includes the following plea for the recognition of the importance of trade secret chemical identities to their owners:

Particularly in the chemical industry, the precise identification of ingredients ... may involve the results of research and development expenditures of considerable magnitude. Rights in trade secrets can be among the most valuable property rights owned by a company. Buildings and equipment can be replaced at predictable costs, but secrets once lost to competitors are gone forever, and with them the incalculable advantages their owners earned.⁴

New chemical substances and new mixtures of existing chemical substances usually take millions of dollars to develop. Public disclosure of their chemical identities would make the fruits of those investments readily available to others who do not have to make similar investments. EPA has acknowledged that "there is no doubt that the fact that certain substances are manufactured or processed for commercial purposes would be confidential under traditional trade secrets law and case law under the Freedom of Information Act fourth exemption (5 U.S.C. 552(b) (4))." Yet information that is public knowledge cannot be a trade secret.

³ "Toxic Chemicals and Public Protection: A Report to the President by the Toxic Substances Strategy Committee" (1980) at 48. The Committee consisted of representatives from the Council on Environmental Quality, eight executive branch departments, and other agencies.

² <u>Kewanee v. Bicron Corp.</u>, 416 U.S. 470, 492 (1974).

⁴ Statement by The Dow Chemical Company, "Toxic Substances Control Legislation – 1973: Hearings Before the Subcommittee on Commerce and Finance of the House Committee on Interstate and Foreign Commerce," 93d Cong., 1st Sess. (1973) at 355-56. Congressional materials cited in this paper are available in the LexisNexis Congressional Hearings Digital Collection.

⁵ 42 Fed. Reg. 64572, 64590 (Dec. 23, 1977) (comment 93).

Forced disclosure of trade secret or confidential chemical identities under EPA's interpretation of section 14 means that innovators may have less incentive to invest the resources necessary to develop the new chemicals and mixtures that could promote the health and well-being of Americans and the environment. Increasingly, "greener" chemicals are being developed to replace those with greater possible risk to health or the environment. Without the potential for economic returns on investment made possible through CBI protection, those greener chemicals may never be introduced.

Lack of CBI protection may also drive innovation and jobs overseas. Companies may seek to manufacture chemicals in other countries where the confidentiality of their chemical identities is protected from disclosure.

Many businesses, and particularly small businesses, often innovate by combining existing chemical substances in new ways. Such combinations are typically not eligible for patent protection. Their combination creates considerable value, however, but only if protected from disclosure. EPA's CBI disclosure policy applies to the components of mixtures, and thus may inhibit innovation in development of new and improved formulations.

In light of these considerations, EPA should critically review its CBI disclosure policy. With some changes to that policy, it can still achieve its transparency goals without disclosing trade secret or confidential chemical identities. For example:

- Where chemical identities in or underlying a study are to be withheld, EPA can require the development of structurally-descriptive chemical names that will give context to the studies for the public, thus enabling both an evaluation of the studies themselves and searches of the toxicological literature for related compounds.⁷
- EPA can require up-front substantiation of claims that chemical identities in or underlying studies are trade secrets or confidential commercial information, thus discouraging inappropriate CBI claims.⁸
- EPA can require reassertion and resubstantiation of previous CBI claims so as to remove confidentiality protection for stale CBI claims, an idea already in development. 9

-

⁽Continued ...)

Ruckelshaus v. Monsanto Co., 467 U.S. 986, 1002 (1984) (citing the Restatement of Torts).

⁷ EPA already requires development of generic names for chemical identities claimed as CBI in submissions under section 5 (40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3)). Its former Inventory regulations required submission of a generic name with a CBI claim for chemical identity. 40 C.F.R. § 710.7(e)(2)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977). EPA also requires submission of a generic name under the Emergency Planning and Community Right-to-Know Act of 1986 (40 C.F.R. § 370.64(a)).

⁸ EPA already requires up-front substantiation for CBI claims for chemical identities submitted under section 5 (40 C.F.R. §§ 720.85(b)(3)(iv), 721.1(c), 725.94), section 4 (40 C.F.R. § 790.7(c)), and section 8(a)'s Chemical Data Reporting Rule (40 C.F.R § 711.30(b)(1)).

⁹ According to the Spring 2011 Regulatory Agenda, RIN 2070-AJ90, "EPA is considering establishing regulations relating to claims for confidential business information (CBI) submitted under the Toxic Substances Control Act (Continued ...)

Moreover, as explained in the following sections, EPA's legal conclusion that it must disclose trade secret or confidential chemical identities in or underlying health and safety studies is simply incorrect. The information provided below, the legislative history in particular, may not have been considered fully by EPA in formulating its CBI disclosure policy.

II. Background on Section 14

With some exceptions, section 14(a) broadly prohibits EPA from disclosing to the public information which is exempt from mandatory disclosure to the public under the Freedom of Information Act (FOIA) exemption (b)(4), for "trade secrets and commercial or financial information obtained from a person and privileged or confidential." Trade secret or confidential chemical identities are included within the protections of section 14(a).

Section 14(b) limits the scope of section 14(a) by providing that it "does not prohibit the disclosure of -- (A) any health and safety study which is submitted under this Act" Section 14(b) is itself limited by several qualifications. Not all studies submitted under TSCA are covered, only those with respect to:

- (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution, or
- (ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5

In addition, section 14(b) contains the following exclusion from its coverage:

This paragraph does not authorize the release of any data which discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.

EPA has promulgated regulations under sections 5 and 8(d), in connection with definitions of the term "health and safety study," saying that chemical identity is always part of, or underlying data to, a health and safety study. If the identity of the chemical being tested is not disclosed in the study itself (e.g., because a trade name is used instead), then the specific chemical identity is reasonably considered to be underlying data for the study. This conclusion, however, does not answer the question of whether the identity must be disclosed to the public when it is a trade secret or confidential commercial information.

_

⁽Continued ...)

⁽TSCA) that would require the periodic reassertion and resubstantiation of such claims. Confidentiality claims which are not reasserted and resubstantiated would expire. EPA expects this action would increase transparency and availability of public health and environmental effects information on chemicals in commerce." ¹⁰ 5 U.S.C. § 552(b)(4).

¹¹ 40 C.F.R. § 716.3 ("Chemical identity is part of, or underlying data to, a health and safety study."); § 720.3(k) ("Chemical identity is always part of a health and safety study."); § 725.3 ("Microorganism identity is always part of a health and safety study of a microorganism.").

Recently, EPA has taken the position that section 14(b) means that a trade secret chemical identity must be disclosed whenever it is part of, or underlying data for, a health and safety study submitted under TSCA. In May 2010, EPA declared:

EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted. Congress did not specifically exempt chemical identities from TSCA section 14(b), and EPA believes that interpreting TSCA section 14(b) in such a manner would be inconsistent with the intent of Congress in enacting that provision.¹²

This interpretation of the statute is not correct. Congress intended for EPA to protect chemical identities in submitted health and safety studies while also providing the public with the health and environmental information it needs to evaluate those studies. In other words, EPA must balance the competing interests, as it has done for nearly 30 years.

III. The Text of TSCA Shows Intent to Protect Trade Secret or Confidential Chemical Identities in Submitted Health and Safety Studies

The text of TSCA itself establishes that Congress intended for EPA to balance the interest in disclosure of health and safety studies against the competing interest in non-disclosure of trade secret or confidential competitive information in or underlying those studies. The studies may be made public, but EPA must protect such information in those studies.

A. Section 14(a) Protects Trade Secret or Confidential Commercial Information in or Underlying Studies

Section 14(a) provides broad protection for trade secret or confidential commercial information submitted to EPA. It states in part:

Except as provided by subsection (b), any information reported to, or otherwise obtained by, the Administrator ... under this Act, which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b) (4) of such section, shall, notwithstanding the provisions of any other section of this Act, not be disclosed by the Administrator [with certain enumerated exceptions¹³].

_

¹² 75 Fed. Reg. 29754, 29756 (May 27, 2010).

One of the exceptions is use in a proceeding under TSCA, but, in language unusual for an environmental statute, section 14(a)(4) provides that disclosure in a proceeding "shall be made in such manner as to preserve confidentiality to the extent practicable without impairing the proceeding." Thus, Congress chose to emphasize the importance of preserving confidentiality even in the case of a limited exception to section 14(a).

That protection extends to trade secret or confidential chemical identities in appropriate cases, as demonstrated by court decisions interpreting FOIA exemption (b)(4). As the EPA General Counsel has found with respect to FIFRA:

Moreover, confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely. If inquiry shows that the information is in fact confidential in the submitter's hands, and that its disclosure would be likely to cause substantial harm to the submitter's competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.¹⁵

Congress emphasized the importance of protecting information subject to section 14(a) from disclosure. Section 14(d) authorizes criminal penalties for wrongful disclosure, and section 14(a)(3) limits EPA's discretion to disclose protected information outside of specified contexts to where EPA determines that disclosure "is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment."

Were it not for section 14(b), there would be no question that trade secret or confidential chemical identities in or underlying health and safety studies submitted under TSCA would be protected from disclosure. Accordingly, the real question is whether anything in section 14(b) undercuts that protection of trade secret or confidential chemical identities.

One obvious point to make is that section 14(b) nowhere refers to chemical identities; instead, it refers to health and safety studies. Section 14(b) provides that section 14(a) "does not prohibit the disclosure of" studies submitted under TSCA, but it specifically does not require that otherwise protected information in or underlying those studies be made public. By explicitly prohibiting disclosure of process and portion of mixture information, section 14(b) clearly contemplates that EPA must protect from disclosure at least some trade secret or confidential information in or underlying submitted studies.

The exclusions from section 14(b) are not exhaustive. For example, EPA has declared in its section 8(d) rules that section 14(b) does not extend, in appropriate cases, to information such as "company name or address, financial statistics, and product codes used by a company, which is contained in a study." Section 14(b) has no explicit exemption for such information.

- 9 -

¹⁴ See, e.g., <u>Appleton v. FDA</u>, 451 F. Supp. 2d 129, 142 & n.7 (D.D.C. 2006) (drug chemical composition); Kennedy v. DHS, No. 03-6076, 2004 WL 2285058, at *7 (W.D.N.Y. Oct. 8, 2004) (protecting names and coding of inks) <u>Center for Auto Safety v. NHTSA</u>, 93 F. Supp. 2d 1, 40-41 (D.D.C. 2000) (identity of inflator gas used for air bags); <u>Northwest Coalition for Alternatives to Pesticides v. Browner</u>, 941 F. Supp. 197 (D.D.C. 1996) (reviewing individual chemical identities under FOIA exemption 4); <u>Citizens Comm'n on Human Rights v. FDA</u>, No. 92-5313, 1993 WL 1610471, at *7 (C.D. Cal. May 10, 1993) (information about how a pioneer drug product is formulated and chemically composed), *aff'd in part & remanded in part on other grounds*, 45 F.3d 1325 (9th Cir. 1995).

opinion No. 70-8 (Mai. 3, 1976), 1976 WE 25250 (E.F.A.G.C.) (emphasis added).

16 "Any respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company [in a study]. This information will not be subject to the disclosure requirements of section (Continued ...)

However, as confidential financial statistics and product codes are both kinds of information protected by section 14(a) and are not themselves health or environmental effects information, section 14(b) should not be read to preclude the application of section 14(a) to such information. More generally, section 14(a) continues to apply to other trade secret or confidential commercial information in or underlying those studies that is not health or environmental effects information, including confidential chemical identities.

B. <u>Protection of Trade Secret or Confidential Chemical Identities in Studies</u> Submitted Under Section 5

One situation in which section 14(b) applies is where studies have been submitted under section 5, in connection with either a premanufacture notice (PMN) or a significant new use notice (SNUN). In some situations, the submitter of a PMN or SNUN must submit health and safety data to EPA. Section 5(b)(3) provides that such data "shall be available, **subject to section 14**, for examination by interested persons." (Emphasis added.) The reference to section 14 reflects Congressional concern for confidential competitive information; otherwise, section 5(b)(3) could simply require disclosure.

In all situations, section 5(d)(1) requires the submitter of a PMN or SNUN to submit "any test data in the possession or control" of the submitter. Section 5(d)(2) requires public release (in the form of a Federal Register notice) of a summary of that test data and any data submitted under section 5(b) or 4:

Subject to section 14 ..., the Administrator shall publish in the Federal Register a notice which—

- (A) identifies the chemical substance for which notice or data has been received;
- (B) lists the uses or intended uses of such substance; and
- (C) in the case of the receipt of data under subsection (b), describes the nature of the tests performed on such substances and any data which was developed pursuant to subsection (b) or a rule under section 4.

(Emphasis added.) Again, Congress felt the need to invoke section 14 so as to protect competitively sensitive information. In addition, section 5(d)(2) specifically addresses chemical identities:

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

-

⁽Continued ...)

¹⁴⁽b) of TSCA." 40 C.F.R. § 716.55(a)(4). When adopting the predecessor provision in 1982, EPA asserted that it was justified by exemption 6 of FOIA, for "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 47 Fed. 38780, 38788 (Sept. 2, 1982). In adopting the current provision, EPA wisely no longer relied on exemption 6, which the Supreme Court has held applies only to individuals, not to companies. See, e.g., FCC v. AT&T, Inc., No 09-1279 (S. Ct. Mar. 1, 2011) (interpreting exemption 7(C) consistently with exemption 6 to apply only to the privacy interests of individuals). Thus, the provision relies on exemption 4, the same exemption that applies to confidential chemical identities.

Thus, trade secret or confidential chemical identities in health and safety studies submitted under section 5 are to be protected by use of generic names unless, in balancing the respective interests at stake, EPA determines that disclosure is necessary.

A provision requiring disclosure of chemical identities of PMN chemicals in Federal Register notices appeared in the 1972 TSCA bill.¹⁷ The accompanying Senate report expressed support for the use of generic names in lieu of specific chemical identities in those Federal Register notices, as now appears in section 5(d)(2):

It is anticipated that a limited amount of data will be published in the Federal Register, since a disclosure of the identity of the chemical substance and intended uses prior to its commercial production would, in many cases, result in the disclosure of trade secrets that would be protected by section 115. However ..., it may be possible to identify a chemical as a member of a family of chemical substances without disclosing trade secret information. This information, coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results.¹⁸

Section 5(d)(2) may be seen as a response to an industry letter calling for complete protection of chemical identity and use information in Federal Register notices:

Member firms have continually objected to the release of unnecessary information via Federal Register publication. Publication of such information has the very definite effect of discouraging product innovation and the release of new and valuable chemical specialty products. We suggest, therefore, that any requirement for Federal Register publication in any toxic substances legislation exclude information pertaining to proposed uses and composition because such data constitutes confidential commercial and trade secret information.¹⁹

Congress did not categorically exclude composition and use information from Federal Register notice requirements, as requested. In section 5(d)(2) it did, however, protect composition information through the use of generic names except where EPA's balancing of interests indicates otherwise.

¹⁷ S. 1478 (1972), § 104(a), S. Rep. No. 92-783 at 3 (1972) ("Subject to section 115 of this title [captioned "Confidentiality"], the Administrator shall promptly publish in the Federal Register the identity of such chemical substance, the uses intended, and a statement of availability of test data.").

¹⁸ S. Rep. No. 92-783 at 19-20 (1972) (emphasis added).

¹⁹ Letter submitted by the Chemical Specialty Manufacturers Association, "Toxic Substances Control Act: Hearings Before the Subcommittee on Consumer Protection and Finance of the House Committee on Interstate and Foreign Commerce," 94th Cong., 1st Sess. (1975) (1975 House Hearings) at 450.

It would make no sense for EPA to be required by section 14(b) to disclose those same trade secret identities protected by section 5(d)(2) when it makes the studies themselves available for disclosure. Thus, while section 14(b) means that public disclosure of studies submitted in connection with a PMN or SNUR is not prohibited, TSCA protects any trade secret or confidential chemical identities in or underlying those studies from disclosure.

C. <u>Protection of Trade Secret or Confidential Chemical Identities in Studies</u> Submitted Under Section 4

A second situation in which section 14(b) applies is where a chemical substance or mixture is the subject of testing requirements under section 4. As with studies submitted under section 5, this means that the resulting studies themselves are not prohibited from disclosure. However, the trade secret or confidential identity of the tested chemical substance or mixture is subject to protection from disclosure under section 14(a). This may be seen in section 4(d), which provides (emphasis added):

Upon the receipt of any test data pursuant to a rule under subsection (a), the Administrator shall publish a notice of the receipt of such data in the Federal Register. within 15 days of its receipt. Subject to section 14, each such notice shall (1) identify the chemical substance or mixture for which data has been received Except as otherwise provided by section 14, such data shall be made available by the Administrator for examination by any person.

That section 4(d) was intended to protect trade secret or confidential identities from disclosure is apparent from the corresponding provision of a 1975 House bill, H.R. 7664, which included at the end the following additional sentence not included the final version of TSCA:

Notice under this subsection shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.²¹

This is virtually the same language that appears in section 5(d)(2). Congress ultimately decided not to require disclosure of generic names in the Federal Register notice for reports on studies submitted under section 4, as it did with section 5, but it clearly intended for EPA to balance the competing interests in making disclosure decisions for studies submitted under section 4, including with respect to trade secret or confidential chemical identities. Thus, section 4(d) protects such chemical identities in the Federal Register notice announcing receipt of studies submitted under section 4.

4(f), H.R. Rep. No. 93-360 at 4 (1973).

- 12 -

²⁰ It is unlikely that health and safety studies submitted under section 4 would involve confidentiality claims for chemical identities. The point here, however, is that Congress anticipated that in some cases there could be a need for confidentiality in section 4 submissions as well as section 5 and other submissions under TSCA.

²¹ H.R. 7664 § 4(f), 1975 House Hearings at 42. The same language appeared in the 1973 House bill, H.R. 5356, §

It would make no sense for EPA to be required by section 14(b) to disclose those same trade secret identities when it makes the studies themselves available for disclosure. Accordingly, section 14(b) does not mandate disclosure of trade secret chemical identities in studies submitted under section 4.

D. Section 8(a) Illustrates How Section 14 Protects Chemical Identities

Under section 8(a), EPA may require manufacturers and processors to report chemical identity information. It specifically mentions "the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required." It restricts EPA's ability to require reporting of "changes in the proportions of the components of a mixture" except in defined circumstances.

Such detailed chemical information is subject to reporting to EPA; but, key to this discussion, it is protected from disclosure to the public. This information is clearly covered by section 14(a). In the Inventory Update Reporting (IUR) rule, now the Chemical Data Reporting (CDR) rule, EPA has allowed CBI claims under section 14(a) for such information.²²

With section 8(a), Congress again recognized that chemical identity information should be protected from disclosure when it is trade secret or confidential. In contrast, section 14(b) is limited to health and safety studies themselves, not to trade secret or confidential information in or underlying them, such as chemical identities.

E. <u>Protection of Trade Secret or Confidential Chemical Identities in Studies</u> Where Disclosure Would Reveal Process Information

Section 14(b) does not apply to process information, even when that information is in the form of a trade secret or confidential chemical identity related to a study submitted under TSCA:

This paragraph does not authorize the release of any data which discloses process used in the manufacturing or processing of a chemical substance or mixture

EPA has acknowledged that some chemical identities can reveal process information. Its May 2010 policy statement identified polymers and UVCB chemicals as examples of such chemical identities. This is another way in which TSCA protects trade secret or confidential chemical identities in submitted studies.

F. <u>Protection of Trade Secret or Confidential Chemical Identities in Studies on</u> R&D Chemicals and Mixtures

- 13 -

²³ 75 Fed. Reg. 29754, 29756 (May 27, 2010).

²² EPA has limited CBI claims for chemical identities to those on the confidential portion of the TSCA Inventory, but it has allowed CBI claims for the connection of the manufacturer to the chemical where the chemical identity is not protected from disclosure. 40 C.F.R. § 710.58(b), now 40 C.F.R. § 711.30(b).

TSCA protects trade secret or confidential identities in studies on R&D chemicals and mixtures by exempting such studies from the provisions of section 14(b) altogether.

Section 14(b) applies to a health and safety study submitted under TSCA that relates to "any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution." The key phrase "offered for commercial distribution" excludes studies of R&D chemicals and R&D mixtures. It has a different meaning than the phrase "for commercial purposes," which EPA has interpreted to include R&D. 24

EPA has noted that "Congress, accordingly, seemed to recognize the importance of confidentiality prior to manufacture of a chemical for commercial purposes." More recently, EPA has acknowledged this exclusion for studies of R&D chemical substances in its January 2010 policy statement regarding CBI claims for studies submitted under section 8(e), many of which relate to R&D chemical substances. That policy statement is limited to studies on chemical substances on the public Inventory, i.e., which are no longer R&D. 26

This R&D exclusion also applies to mixtures which are themselves the subject of R&D, since section 14(b) refers to "any chemical substance **or mixture** which ... has been offered for commercial distribution" (emphasis added). For example, a processor may be conducting R&D on a mixture of existing chemicals. A submitted study on such an R&D mixture would be excluded from section 14(b), even if its components were entirely on the Inventory. The mixture itself must have been offered for commercial distribution for section 14(b) to apply to submitted studies on the mixture. ²⁷

G. Implications for Other Studies Submitted Under TSCA

Some studies submitted to EPA under TSCA are not submitted under either section 4 or 5, nor do the identities of the chemicals tested reveal process information, nor do the studies concern R&D chemical substances or mixtures. But the concern expressed throughout TSCA for balancing the interest in disclosure of health and safety studies with the interest in non-disclosure of competitively sensitive information in or underlying those studies is implicit in section 14 with respect to these other studies as well.²⁸

Section 14(a) protects from disclosure trade secret or confidential commercial information, such as confidential chemical identities. Section 14(b) provides an exception for

-

²⁴ See 40 C.F.R. § 720.3(r)(1)(ii) (defining the term "manufacture or import for commercial purposes" to include R&D); 44 Fed. Reg. 17673-74 (Mar. 23, 1979); <u>Dow Chemical Co. v. EPA</u>, 605 F.2d 673, 689 (3d Cir. 1979). ²⁵ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).

²⁶ 75 Fed. Reg. 3462 (Jan. 21, 2010).

²⁷ Accordingly, EPA should deny FOIA requests for the release of chemical identities of mixtures that are the subject of submitted health and safety studies where the mixture itself is not, on the date of proposed disclosure, offered for commercial distribution.

²⁸ To resolve questions arising from the text of a statute, it is well established that legislative intent must be ascertained by looking to the entire statute, read comprehensively as a whole. See, e.g., <u>Samantar v. Yousuf</u>, 130 S. Ct. 2278, 2289 (2010) ("[w]e do not . . . construe statutory phrases in isolation; we read statutes as a whole.") (citation omitted).

health and safety studies, but not for trade secret or confidential commercial information contained in those studies. As discussed above, Congress repeatedly distinguished trade secret or confidential commercial information in or underlying those studies from the studies themselves. Accordingly, while section 14(b) does not prohibit the disclosure of many studies submitted under TSCA, EPA must still balance the competing interests with respect to competitively sensitive information in or underlying such studies. This conclusion finds additional support in the legislative history of section 14, discussed below.

IV. The Legislative History Demonstrates That Congress Wanted EPA to Protect Trade Secret or Confidential Chemical Identities When Disclosing Health and Safety Studies

Several TSCA bills were introduced from 1971 to 1976, and all had provisions protecting trade secrets, counterparts to what became section 14(a). A counterpart to section 14(b) did not appear until the 1976 House bill, however. Section 14(b) was added to resolve for TSCA an issue which for FIFRA was then under active debate, and which came to the forefront in 1975: whether health and safety data submitted to EPA qualified as trade secrets or confidential commercial information. That issue did not relate to proprietary data in studies, such as trade secret or confidential chemical identities, which under FIFRA were protected.

Accordingly, to understand section 14(b) properly, it is important to review the history of the debate on confidentiality of health and safety studies under FIFRA that led to section 14(b). ²⁹ That history is summarized below, followed by additional TSCA legislative history that refers to this FIFRA debate.

A. 1972 FIFRA Amendments

In 1972, Congress extensively revised FIFRA with enactment of the Federal Environmental Pesticide Control Act of 1972 (FEPCA).³⁰ Among many other changes to FIFRA, FEPCA required public disclosure of studies submitted in connection with applications:

Except as provided by subsection (c) (1) (D) of this section **and section 10**, within 30 days after the Administrator registers a pesticide under this Act he shall make available to the public the data called for in the registration statement together with such other scientific information as he deems relevant to his decision.³¹

While FEPCA called for disclosure of studies, it also protected trade secret or confidential information in or underlying those studies. FIFRA § 10(b) protected trade secrets and confidential information from disclosure. It specifically included, "formulas of products," i.e., chemical identities and their percentages, within this protection from public disclosure:

_

²⁹ See, e.g., <u>National Treas. Employees Union v. Federal Labor Relations Auth.</u>, 691 F.2d 553, 559 (D.C. Cir. 1982) ("[T]he intent of Congress is paramount, and this intent may appropriately be ascertained from relevant legislative history.").

³⁰ Pub. L. 92-516 (1972).

³¹ FIFRA § 3(c)(2), as added by FEPCA (emphasis added).

Notwithstanding any other provision of this Act, the Administrator shall not make public information which in his judgment contains or relates to trade secrets or commercial or financial information obtained from a person and privileged or confidential, except that, when necessary to carry out the provisions of this Act, **information relating to formulas of products** acquired by authorization of this Act may be revealed to any Federal agency consulted and may be revealed at a public hearing or in findings of fact issued by the Administrator ³²

The exception beginning "when necessary to carry out the provisions of this Act" has its counterpart in section 14(a) of TSCA, which enumerates four exceptions to protection of CBI related to administration of that act, including disclosure to other federal agencies and in proceedings. Such exceptions are common in statutory guarantees of CBI protection. The exception is not a broad license for EPA to ignore the mandate to protect CBI, but rather a prudential limitation on the extent of protection.

Other aspects of FEPCA also protected confidential identities of inert ingredients from disclosure. Active ingredients and their percentage in formulated products had to appear on the pesticide label, but confidential inerts only had to be reported on the label as a total percentage. ³³ FIFRA § 12(a)(2)(D) made it unlawful for any person to reveal "any information acquired by authority of this Act which is confidential under this Act," and FIFRA § 14(b) made disclosure of "formulas" in some cases a criminal act.

In addition, FIFRA § 3(c)(1)(D) provided an opportunity for data compensation for submitters of studies relied on by EPA in reviewing the application of a second applicant.

A Senate report on the FEPCA legislation commented that disclosure of health and safety studies without disclosure of trade secret identity information <u>would</u> serve the public need for information about the effects of pesticides under review by EPA: "Merely disclosing test results without identifying the pesticide will enable toxicologists and other scientists to evaluate the results that are claimed."³⁴

B. Debate About Disclosure of Health and Safety Studies Under FIFRA

An issue arose under FEPCA about whether the health and safety studies submitted by applicants and registrants were also covered by FIFRA § 10(b). That issue had immediate relevance to pesticide applicants and registrants, since FIFRA § 3(c)(1)(D), which allowed EPA

³² Emphasis added. Note that "trade secrets or commercial or financial information obtained from a person and privileged or confidential" is a reference to exemption (b)(4) of FOIA. TSCA § 14(a) also relies on exemption (b)(4) of FOIA as the basis for protecting trade secret information from disclosure.

³³ As amended by FEPCA, FIFRA § 2(q)(2)(A) provides that a pesticide is misbranded if its label does not bear an "ingredient statement," a term defined in § 2(n) to include "the name and percentage of each active ingredient, and the total percentage of all inert ingredients, in the pesticides" Thus, Congress did not require disclosure of the identity of inert ingredients.

³⁴ S. Rep. No. 92-270 at 20 (1972), 1972 U.S.C.C.A.N. 4092, 4104-05.

to use a previous applicant's studies in assessing the registration application of a second applicant, subject to data compensation, only applied if "such data is not protected from disclosure by section 10(b)." In other words, if those studies qualified as trade secrets, EPA could neither use them for registering competitive pesticides nor disclose them publicly.

EPA took the position that it could use previously submitted studies for reviewing applications by other companies and could disclose health and safety studies, notwithstanding trade secret claims under section 10(b). In 1973, EPA issued a policy statement saying it planned to use the health and safety studies submitted by others in reviewing new applications under section 3(c)(1)(D) (i.e., notwithstanding its reference to section 10(b)). In a 1975 proposal under FOIA, EPA proposed to exclude health and safety studies from confidentiality review procedures because "EPA believes as a matter of public policy, data concerning the effects of such pesticides on humans cannot qualify for confidential treatment," and because FIFRA suggested that "safety, toxicity, and efficacy test data should be available for public inspection." However, information "[w]hich relates to formulas of products" would only be disclosable under limited circumstances. 37

A key development occurred in March 1976, when the EPA General Counsel issued an opinion on the meaning of FIFRA § 10(b), saying that with certain exceptions, "I conclude that none of the test data in the categories listed above [including hazard data] are entitled to confidential treatment under §10(b)." Significantly, while finding that health and safety studies generally are subject to public disclosure, the EPA General Counsel held that disclosure of confidential chemical identities was both prohibited by FIFRA § 10(b) and not required by the public interest in disclosure:

Disclosure of the confidential formula of a pesticide, as defined above, would further neither the § 3(c)(1)(D) mandatory licensing scheme nor the § 3(c)(2) policy favoring data scrutiny. However, disclosure would often reveal a firm's manufacturing process. Moreover, confidential ingredient statements often have been held by courts to be trade secrets. Thus, such information should not be disclosed routinely. If inquiry shows that the information is in fact confidential in the submitter's hands, and that its disclosure would be likely to cause substantial harm to the submitter's competitive position, the information is entitled to confidential treatment. Requests for disclosure of such information should be initially denied, citing 5 U.S.C. 552(b)(4), 5 U.S.C. 552(b)(3), and 7 U.S.C. 136h(b), and necessary further inquiry should be addressed to the data submitter.³⁸

The General Counsel also found manufacturing and quality control information to be protected from disclosure under section 10(b), even when found in a health and safety study, as well as

_

^{35 38} Fed. Reg. 31862 (Nov. 19, 1973).

³⁶ 40 Fed. Reg. 21987, 21991 (May 20, 1975).

³⁷ Id. at 22001.

³⁸ Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.) (emphasis added).

information supporting applications not yet approved. EPA cited this opinion in September 1976 in finalizing its 1975 FIFRA FOIA proposal.

Once the General Counsel issued his opinion, EPA began issuing notices informing registrants of its intention to make their studies available to the public. Several registrants sought to prevent disclosure by initiating lawsuits that challenged the General Counsel's opinion that health and safety studies were not confidential. The first such suit was filed in June 1976. 40 while the House bill with a provision that became section 14(b) was still in committee. 41

C. **Congressional Consideration of TSCA in 1975-1976**

This debate under FIFRA figured significantly in the 1975 hearings, the 1976 House bill, and the enactment of TSCA § 14(b).

1. Stakeholder Comments on Disclosure of Health and Safety Studies

The issue of making health and safety studies public was raised numerous times by NGOs in their testimony to EPA in 1975. See, for example, the following statements:

If science is to flourish the findings must be public. Since the dawn of the scientific revolution any suppression of scientific information has been regarded as antiscientific and repressive. Yet the walls of trade secrecy and corporate confidentiality restrict the dissemination of knowledge about the nature and properties of chemicals.

In particular, the final Subcommittee bill should specify that data from health and safety studies reported to the Administrator pursuant to sections 5 and 8 ... are not to be considered proprietary information or subject to protection as trade secrets. The effective implementation of a Toxic Substances Control Act requires that information concerning the hazardous nature of substance be available to the public.⁴³

An NGO representative explicitly referenced the ongoing debate under FIFRA about whether health and safety studies were protected from disclosure as trade secrets:

⁴³ Statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 185.

³⁹ 41 Fed. Reg. 36902, 36924 (Sept. 1, 1976). The final regulation, unamended since 1976, reads, "Information to which this section applies, and which relates to formulas of products, may be disclosed at any public hearing or in findings of fact issued by the Administrator, to the extent and in the manner authorized by the Administrator or his designee." 40 C.F.R. § 2.307(g)(4). This language is adapted from FIFRA § 10(a), as added by FEPCA.

⁴⁰ See A. Gabbay, The Confidentiality of Test Data Under FIFRA, 2 Harvard Environmental L. Rev. 378, 388 (1978) (citing cases).

41 H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), Legis. Hist. at 371-72.

⁴² Statement of Alfred J. Fritsch, Center for Science in the Public Interest, 1975 House Hearings at 172.

Under the Pest Control Act, reported out of this committee in 1972, toxicology data on pesticides is not a trade secret. Under the current bill, toxicology appears to be a trade secret, since there is no explicit provision for release 44

Even as they advocated for disclosure of health and safety studies submitted under TSCA, however, several NGO representatives acknowledged that trade secret chemical identities should remain confidential. One said that "secret formulas" should remain confidential, so long as effects information is made public:

In summary, we support the language in the Brodhead Bill, which would withhold bona fide trade secrets such as secret formulas and secret manufacturing methods, but which would disclose health and safety data or publicly-known manufacturing methods.⁴⁵

Another stated, "Well, we are certainly not advocating that legitimate trade secret information be turned over." However, he maintained that health and safety studies were not trade secrets. ⁴⁶ A third said, "If there are studies which give you detailed information on the chemical itself, I think the companies might have a legitimate [trade secret] claim." ⁴⁷

Industry also emphasized the importance of protecting trade secrets, particularly confidential chemical identities. For example, one industry represented stated:

Legislation should offer strict control of manufacturers' trade secrets. The chemical entity's molecular structure, proposed usage and amounts to be manufactured should not be published for all to see and use. Similarly, disclosure of detailed information on formulations, that is, a mixture of materials, should be avoided. Disclosure of all such information can have particularly severe competitive repercussions abroad, in those foreign countries whose manufacturers are not or do not feel restricted by patents or other agreements.⁴⁸

A significant development occurred in September 1975 with the release of a report by the National Academy of Sciences, which EPA had commissioned so as to influence the drafting of TSCA. The report recommended that health and safety studies be made publicly available, but not proprietary information in those studies:

Any information available to an agency on the hazards of a chemical that is regulated by that agency should not be considered proprietary and should be available for public inspection in a timely fashion during and after the decision-making process.

_

⁴⁴ Statement of Peters D. Willson, National Wildlife Foundation, "Toxic Substances Control Act: Hearings Before the Subcommittee on the Environment of the Senate Committee on Commerce," 94th Cong., 1st Sess. (1975) (1975 Senate Hearings) at 158.

⁴⁵ Statement of Anita Johnson, Public Citizen Health Research Group, 1975 House Hearings at 355.

⁴⁶ Statement of Dr. Sidney Wolfe, Health Research Group, 1975 Senate Hearings at 168-69.

⁴⁷ Statement of Jacqueline Warren, Environmental Defense Fund, 1975 Senate Hearings at 171.

⁴⁸ Statement of Orin Smith, M. & T. Chemical Co., 1975 Senate Hearings (Part 2) at 121.

The report focused on effects and exposure data such as "data on the intrinsic toxicological properties of a given substance" and "data on patterns and quantities of use." The report agreed, however, that "proprietary" data should be protected from disclosure unless essential to evaluation of the hazard. While the report did not refer specifically to proprietary chemical identities, EPA subsequently addressed that issue, finding that a structurally-descriptive generic name can mean that disclosure of the specific chemical identity "is not necessary to interpret a health and safety study." See section VI of this paper. The report's recommendation was quoted in the TSCA hearing statements of two NGO representatives. 51

2. The 1976 Provision on Disclosure of Health and Safety Studies

In May 1976, two months after issuance of the General Counsel's opinion, the House responded to these comments by including in a new TSCA bill a provision that would explicitly exclude health and safety studies from confidentiality protection, H.R. 14032. With minor editing, that provision became TSCA § 14(b). The House report accompanying H.R. 14032 explained:

The purpose of subsection (b) is to clarify that health and safety information is not entitled to confidential treatment either under subsection (a) or the Freedom of Information Act. The subsection should not be construed to imply that in the absence of such a provision, health and safety information would be entitled to such confidential treatment.⁵³

This statement is a clear reference to the then-ongoing debate under FIFRA of whether health and safety studies were protected from disclosure as trade secrets, and reflected the opinion of the EPA General Counsel that they were not so protected.

The House bill and report did not, however, endorse public disclosure of confidential information of competitive value that might be contained in the health and safety studies. Notwithstanding section 14(b), the House report provided assurance that section 14 would protect the "competitive position" of submitters of information to EPA:

However, the Committee recognizes that some information which the Administrator may obtain will be of tremendous competitive value to the person providing it. Accordingly,

⁴⁹ National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment (1975), http://books.google.com/books?id=1zArAAAAYAAJ&printsec=frontcover&dq=%22Decision+Making+for+Regulating+Chemicals+in+the+Environment+%22&source=bl&ots=0KpnIvNpTP&sig=-pNWX4LW5HFJCqxwSvUYPUrKiHY&hl=en&ei=gfexTZTZOKbf0QHxtqGKCQ&sa=X&oi=book_result&ct=result&resnum=1&ved=0CBoQ6AEwAA, at 28 (italics in original).

 ⁴⁰ C.F.R. §§ 720.90(c)(3), 725.92(c)(2).
 Statement of Linda M. Billings, Sierra Club, in 1975 House Hearings at 165, and statement of Jacqueline M. Warren, Environmental Defense Fund, 1975 House Hearings at 178.

⁵² H.R. 14032, introduced May 26, 1976, reported with an amendment July 14, 1976, § 14(b), H.R. Rep. No. 94-1341 at 176-77 (1976), Legislative History of the Toxic Substances Control Act (1976) (Legis. Hist.) at 371-72. 53 H.R. Rep. No. 94-1341 at 51, Legis. Hist. at 458.

section 14 contains specific prohibitions against release of such information so that the competitive position of those supplying the information will be protected.⁵⁴

It would be inconsistent with this statement that "section 14" protects "the competitive position of those supplying the information" to consider that the exemption from confidentiality protection for health and safety studies mandates disclosure of competitively sensitive composition information. While section 14(b) does not list composition information specifically as exempt, neither does it specifically mandate disclosure of composition information. Indeed, in describing what a health and safety study is, the Conference Committee emphasized information related to effects, saying nothing about composition information:

It is intended that the term be interpreted broadly. Not only is information which arises as a result of a formal, disciplined study included but other information relating to the **effects** of a chemical substance or mixture on health and the environment is also included. Any data which bears on **the effects** of a chemical substance on health or the environment would be included. ⁵⁵

The EPA General Counsel opinion specifically found in the FIFRA context that non-disclosure of confidential composition information would not impact the purposes of public disclosure of health and safety studies; the same reasoning applies to the TSCA context as well.

As proposed and adopted, section 14(b) has an exemption for "portion of mixture" information. The House report commented on this provision:

In referring to data "disclosing the portion of the mixture comprised by any of the chemical substances in the mixture," the Committee intends to protect confidential trade secret information respecting the specific formulation of a mixture. However, the Committee does not intend to prohibit the Administrator from disclosing the chemical substances comprising the mixture by their order of quantity in the mixture. ⁵⁶

The "specific formulation of a mixture" clearly refers to both the names of the ingredients as well as their percentages, as seen in the FEPCA references to protecting "information relating to formulas of products" and "information relative to formulas of products," where those provisions have always been interpreted to include the identities of confidential inerts as well as their respective percentages.

The reference to "order of quantity in the mixture" is a reference to the Fair Packaging and Labeling Act (FPLA), enacted ten years earlier, which mandates that ingredients in consumer products be disclosed on labels "in order of decreasing predominance" while

58 FIFRA § 14(b)(3)/

⁵⁴ H.R. Rep. No. 94-1341 at 50 (1976), Legis. Hist. at 457.

⁵⁵ H.R. Rep. No. 94-1679 at 58 (1976), Legis. Hist. at 671 (emphasis added).

⁵⁶ H.R. Rep. No. 94-1341 at 51 (1976), Legis. Hist. at 458 (emphasis added).

⁵⁷ FIFRA § 10(b).

protecting trade secrets. It provides that the Federal Trade Commission (FTC) or Food and Drug Administration (FDA) may promulgate regulations to:

require that the label on each package of a consumer commodity bear ... in case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged⁵⁹

In other words, the order of ingredients by decreasing predominance was not considered a trade secret, but such mandated disclosure was coupled with a prohibition on disclosure of trade secrets (both ingredient names if trade secret and portion of mixture information). In 1973, FDA adopted regulations for cosmetic labeling under the FPLA which required disclosure of intentionally added ingredients "in descending order of predominance," but with a mechanism whereby FDA could rule on claims that ingredient identities were trade secrets, in which case they would be identified as "other ingredients." In 1975, FDA amended those regulations and made them effective starting in 1976. Thus, the issue of ingredient disclosure in descending order was a current topic when the provision that became section 14(b) was introduced and considered.

In short, the reference to disclosure of mixture components "by their order of quantity in the mixture" is not an implicit call for public disclosure of trade secret chemical identities, as EPA has suggested. Rather, it is a repetition of a decade-old legislative determination that order of predominance is not a trade secret. Since that determination from the FPLA contained, within the same sentence, a prohibition on disclosure of trade secret ingredient names, the reference in section 14(b) to "order of quantity" actually strengthens the conclusion that TSCA protects trade secret chemical identities.

During Senate consideration of the conference-approved bill, Senator Magnuson referred to "mixture composition" information as an exception to section 14(b). ⁶⁴ This statement by a member of the Conference Committee, one of the leading proponents of TSCA in the Senate, indicates the expectation that information in health and safety studies on "mixture composition," not just portion of mixture information, would not be disclosed as part of health and safety studies.

In summary, the legislative history of TSCA demonstrates continued Congressional concern for protecting critical competitive information from public disclosure, specifically including trade secret or confidential chemical identity information.

- 22 -

⁵⁹ Fair Packaging and Labeling Act, Pub. L. 89-755 (1966), § 5(c)(3), 15 U.S.C. § 1454(c)(3) (emphasis added). ⁶⁰ 21 C.F.R. § 1.205(a), 38 Fed. Reg. 28912, 28913 (Oct. 17, 1973). FTC has not adopted implementing regulations. See 36 Fed. Reg. 12284, 12286 (June 30, 1971), which reserved 16 C.F.R. §§ 502.200-502.299 ("Common Name and Ingredient Listing").

^{61 40} Fed. Reg. 8918 (Mar. 3, 1975). The current provision is codified at 21 C.F.R. § 701.3.

^{62 40} Fed. Reg. 8924 (Mar. 3, 1975).

 ⁶³ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979); EPA, Comment and Response Document for Revised Policy Statement of Section 8(e) of TSCA (2003), OPPT-2002-0067-0002, Docket No. OPPT-2002-0067, at 35-36.
 ⁶⁴ Cong. Rec., Sept. 28, 1976, Legis. Hist. at 730.

V. TSCA as Part of a Series of Statutes Mandating Disclosure of Health and Environmental Information on Chemicals But Not Confidential Chemical Identities

TSCA was the second of six chemical-related statutes that Congress enacted within a fifteen-year period to mandate that health and environmental information submitted to EPA be made public. Besides TSCA, the statutes include the Federal Environmental Pesticide Control Act of 1972 (FEPCA); the Federal Pesticide Act of 1978 (FPA); the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA); the Emergency Planning and Community Right-to-Know Act of 1986 (EPCRA); and the Superfund Amendments and Reauthorization Act of 1986 (SARA), Title I. These other statutes all protect confidential competitive information in or underlying the health and environmental information from disclosure. In light of these statutes, it is even clearer that TSCA does so also.

A. Federal Environmental Pesticide Control Act of 1972

As noted in Section III.A. above, FEPCA required disclosure of health and safety studies submitted to EPA under FIFRA, but it protected confidential competitive information from disclosure, using the standards of FOIA exemption 4. Several provisions explicitly protected confidential formula information, including the identity of confidential inerts, from disclosure.

B. Federal Pesticide Act of 1978

The controversy under FEPCA about whether health and safety studies were protected from disclosure continued past the enactment of TSCA. In 1978 with FPA, Congress applied the solution adopted in TSCA § 14(b) to FIFRA, saying that health and safety studies were not protected from disclosure, but proprietary information in those studies, including trade secret identities of inerts, were protected from disclosure, except under unusual circumstances.

Twelve months after enactment of TSCA, a House committee reported a FIFRA bill which would:

Clarify the prohibition against public disclosure of "trade secret" information obtained by the Environmental Protection Agency through the registration process. Data showing test results would not be considered "trade secrets." Data relating to the manufacturing process or quality control process, **or to the identity or percentage quantity of inert ingredients** ... could not be made public unless the Administrator determined it necessary to protect against an unreasonable risk of injury to health or the environment subject to prescribed procedures

H.R. 8681 also clarifies the trade secret provisions of the Act by balancing the legitimate right of the public to know the basis for agency decisions and the right of a business to see that the manufacturing process and other trade secret information controlled by the Act are not disclosed to the commercial advantage of competing business owners

This provision is intended to protect the secrecy of manufacturing methodology, the **confidential formula of a formulated product**, and the means of analysis of a formulated product to determine its inert ingredients.⁶⁵

In 1978, Congress accepted the House language and added a new FIFRA § 10(d) that declared that health and safety studies submitted under FIFRA in connection with registered pesticides "shall be available for disclosure to the public." However, that provision was limited to include the limitations on disclosure identified in the General Counsel's 1976 opinion:

Provided further, That this paragraph does not authorize the disclosure of information that--

- (A) discloses manufacturing or quality control processes, ...
- (C) discloses the identity or percentage quantity of any deliberately added inert ingredient of a pesticide,

unless the Administrator has first determined that disclosure is necessary to protect against an unreasonable risk of injury to health or the environment.⁶⁶

In other words, Congress required disclosure of health and safety studies, but not the trade secret or confidential identities of the chemicals tested, except where EPA's balancing of the competing interests required a different outcome. This is the same resolution that Congress provided in TSCA § 14, two years earlier, only somewhat less explicitly.

C. <u>Comprehensive Environmental Response, Compensation, and Liability Act</u> of 1980

Two years later, in 1980, Congress enacted CERCLA. Section 104(e)(2)(A) provided that all information obtained under the response authority "shall be made public" unless the person providing the information establishes that disclosure would "divulge information entitled to protection under section 1905 of title 18 of the United States Code," i.e., the Trade Secrets Act. There is an exception for "health or safety effects data," which is not protected from disclosure. This exception more clearly expresses the intent of TSCA's exception for health and safety studies. Note that in EPCRA (discussed next), effects data is also not protected from disclosure, but chemical identities may be protected.

D. Emergency Planning and Community Right-to-Know Act of 1986

In 1986, Congress enacted EPCRA to require disclosure of chemical-related information to EPA, state and local authorities, and the public. The provision on trade secrets, section 322, protects from public disclosure only "specific chemical identities (including chemical name and

68 EPCRA is Title III of SARA, Pub. L. 99-499, 42 U.SC. § 11001 et seq.

⁶⁵ H. Rep. No. 95-663, at 16, 18 (1977), 1978 U.S.C.C.A.N. 1989, 1991-92, 2005-06 (emphasis added).

⁶⁶ Federal Pesticide Act of 1978, Pub. L. 95-396 (1978), § 15(2), 7 U.S.C. § 136h(d) (emphasis added).

⁶⁷ Pub. L. 96-510 (1980), § 104(e)(2)(A), 42 U.S.C. § 9604(e)(7)(A).

other specific identification)." Where the identity of a chemical is withheld from the public, information about the adverse effects of the chemical must be disclosed. 70

This provision reflects Congressional balancing of the competing interests in disclosure and non-disclosure. Information other than chemical identity is not protected. To provide the public with some information about chemicals whose identities are withheld, section 322 requires that the submitter identify "the generic class or category" of the chemical. 71 An up-front substantiation of trade secrecy is required, including a showing that the chemical identity "is not readily discoverable through reverse engineering," i.e., that it actually is a trade secret.

The legislative history refers to EPA's experience with generic names under TSCA, as required under TSCA § 5(d)(2):

The Administrator may give guidance for choosing such [generic] classes or categories in implementing regulations, drawing upon experience under the Toxic Substances Control Act. 73

More than FIFRA or TSCA, EPCRA is intended to provide the public with information about chemicals. That Congress chose to protect trade secret chemical identities even under this statute shows the continuing Congressional concern with balancing the interest in disclosure of health and safety information with the interest in protecting confidential competitive information, a balancing also present in TSCA. Congress mandated non-disclosure of trade secret chemical identities if certain requirements are met, but disclosure of structurally-descriptive generic names, i.e., the same resolution reached in TSCA $\S 5(d)(2)$.

E. Superfund Amendments and Reauthorization Act of 1986, Title I

EPCRA is Title III of SARA and essentially a stand-alone statute. Title I amended CERCLA to cut back on the broad protection from disclosure granted by simple reliance on the Trade Secrets Act. It added several restrictions, including that the person submitting the information establish that "[t]he specific chemical identity, if sought to be protected, is not readily discoverable through reverse engineering," thereby conforming CERCLA to the trade secret provisions of EPCRA.⁷⁴ It also prohibited confidentiality protection for information on the physical properties and health and environmental hazards of the hazardous substances, as well as "[t]he trade name, common name, or generic class or category of the hazardous substance."75 Specific chemical identities, however, could be protected from disclosure.

⁶⁹ EPCRA § 322(a)(1), 42 U.S.C. § 11042(a)(1). ⁷⁰ EPCRA § 322(h), 42 U.S.C. § 11042(h).

⁷¹ EPCRA § 322(a)(2), 42 U.S.C. § 11042(a)(2).

⁷² EPCRA § 322(b), 42 U.S.C. § 11042(b).

⁷³ H. Conf. Rep. No. 99-962 (1986) at 303, 1986 U.S.C.C.A.N. 3276, 3396.

⁷⁴ Id. at 197, 1986 U.S.C.C.A.N. at 3290.

⁷⁵ Pub. L. No. 99-499 (1986), § 104(n), amending CERCLA § 104(e) (adding CERCLA § 104(e)(7)(E) and (F)).

F. <u>Implications for TSCA</u>

Each of these five statutes regulating chemicals mandated disclosure of health and safety information, but protected confidential chemical identities from disclosure, either explicitly or by implication, with provisions similar to what appears in TSCA § 14. None prohibited trade secret claims for chemical identities, although some imposed criteria for those claims.

TSCA similarly provides broad protection for trade secrets and confidential information in section 14(a). Its main reservation from that protection, in section 14(b), is for health and safety studies, which are not protected from disclosure. This limitation is similar to the requirement in several of these statutes that health and environmental effects data must be made public. Just as none of those statutes required disclosure of confidential chemical identities, so TSCA does not do so either.

VI. <u>EPA Recognition of Its Need to Balance Disclosure of Health and Safety Studies</u> With Protection of Trade Secret or Confidential Chemical Identities

Early in its implementation of TSCA, EPA recognized that "Congress was clear in section 14 that confidentiality should be preserved to the maximum extent practicable without impairing the regulatory scheme of TSCA." Despite the language of section 14(b), it concluded:

Accordingly, EPA is not persuaded that Congress intended the Agency to take a mechanical approach to disclosure of a specific chemical identity as part of a health and safety study.⁷⁷

The 1983 final PMN rule developed the idea that, consistent with section 14(b), EPA could balance the public's interest in access to health and safety information with industry's competitive interest in protecting trade secret chemical identities. This balancing was to be achieved through disclosure of structurally-descriptive generic names, an approach endorsed by TSCA § 5(d)(2) and proposed in the 1972 Senate report. The preamble stated:

As EPA stated in the January 1979 proposal, the Agency considers the specific chemical identity always to be part of a health and safety study even when it does not appear in the study. Consequently, the chemical identity would be subject to the disclosure requirements of section 14(b). However, in many cases the chemical identity is one of the most commercially sensitive pieces of information in the section 5 notice. Because of the substantial concern expressed by industry about the harm of disclosing confidential chemical identities, EPA explored ways of limiting the commercial harm of such disclosure while still meeting the requirements of section 14(b) of TSCA and providing the public with adequate information about health and safety studies

- 26 -

⁷⁶ 42 Fed. Reg. 64572, 64591 (Dec. 23, 1977).

⁷⁷ 44 Fed. Reg. 2242, 2256 (Jan. 10, 1979).

⁷⁸ S. Rep. No. 92-783 at 19-20 (1972).

This issue generated a great deal of comment. Industry has expressed its concerns about disclosure of confidential chemical identities at any time, while public interest groups and others are concerned that health and safety studies would be meaningless without knowledge of the specific chemical identity involved. In an attempt to meet both these concerns, EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA

Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies.

This solution will result in disclosure of a confidential chemical identity only when it is necessary to interpret a health and safety study, unless disclosure would reveal confidential process or mixture information that is protected under section 14(b). This meets concerns expressed by both industry and public interest groups. Industry was concerned that a rule mandating disclosure even when disclosure would not serve any public interest would unnecessarily penalize companies conducting health and safety studies. On the other hand, public interest groups were concerned that disclosure of health and safety studies without the identity of the substance involved would be meaningless if knowledge of the specific identity were necessary to understand the study. Under this approach, companies will be able to present arguments that disclosure of the specific chemical identity is not necessary to interpret a study and, at the same time, members of the public requesting access to studies will be able to argue why disclosure of the specific identity is necessary.

This solution to the issue of confidential chemical identities also has an impact on development of generic chemical names. Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. Sufficiently specific generic names will tend to support arguments that disclosure of the specific chemical identity is not necessary to understand the study.⁷⁹

In other words, EPA recognized that, like other proprietary commercial information, confidential chemical identities (including those that do not reveal process or portion of mixture information) in a health and safety study fall within the protection of section 14(a). That protection mandate must be balanced against the disclosure mandate of section 14(b). The competing interests can and should be balanced through disclosure of appropriate generic names.

⁷⁹ 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added).

A decade later, EPA reaffirmed this approach in the preamble to 1993 proposed amendments to the PMN rules⁸⁰ and in the preamble to the 1994 proposed rule on microbial products of biotechnology.⁸¹

EPA has announced that it plans to initiate rulemaking to delete these generic name provisions in its regulations, apparently on the basis that under section 14(b) it had no authority to adopt them. EPA certainly had authority to adopt those provisions, just at it had authority under section 8(d) to exclude proprietary information such as company name, financial statistics, and product codes from studies otherwise disclosed to the public. EPA's authority for all these provisions is section 14(a). All this information may be a part of a study submitted under TSCA, but it is nevertheless protected from disclosure. Because chemical identity can also impact public understanding of the study, however, EPA properly adopted provisions for disclosure of appropriate generic names so as to balance the competing interests.

VII. Steps EPA Should Take to Protect Confidential Chemical Identities

In light of the information provided in this paper, EPA should take the following specific steps to provide appropriate protection for confidential chemical identities in submitted health and safety studies and in other contexts.

A. <u>EPA Should Revise Its Regulations and Guidance to Allow Confidentiality</u> Claims for Confidential Chemical Identities in Studies Where Appropriate

EPA's regulations and guidance currently preclude all or most confidentiality claims for chemical identities in or underlying studies. ⁸⁴ In light of the foregoing discussion, EPA should amend those regulations and revise that guidance to allow CBI claims for chemical identities where appropriate.

EPA's Spring 2011 Regulatory Agenda identifies a planned initiative, RIN 2070-AJ87, to adopt amendments to its PMN and MCAN rules to delete provisions allowing CBI claims for confidential chemical and microorganism identities in data from health and safety studies submitted under TSCA prior to the commencement of manufacture. It targets 40 C.F.R. §§ 720.90(c) and 725.92(c). EPA submitted this proposal to the Office of Management and Budget on December 27, 2011. EPA should not proceed with this initiative.

Section VI of this paper discusses EPA's reasoning for adopting those requirements in the 1980s and 1990s. At the time, EPA took extensive comments and thoroughly considered the scope of section 14 and its legal authority. Nothing has occurred since then that should cause

81 59 Fed. Reg. 45526, 45553-54 (Sept. 1, 1994).

-

^{80 58} Fed. Reg. 7661, 7666 (Feb. 8, 1993).

⁸² EPA, Spring 2011 Regulatory Agenda (July 7, 2011) at 277.

⁸³ See 40 C.F.R. § 716.55(a)(3).

⁸⁴ See 40 C.F.R. § 716.55 (section 8(d) regulations); 40 C.F.R. § 720.90(b) (PMN regulations); 40 C.F.R. § 725.92(b) (MCAN regulations); 68 Fed. Reg. 33129, 33136 (June 3, 2003) and 75 Fed. Reg. 3462 (Jan. 31, 2010) (section 8(e) guidance); 75 Fed. Reg. 29754 (May 27, 2010) (general guidance).

EPA to conclude now, 35 years after enactment of TSCA, that its longstanding interpretation of section 14 allowing confidentiality claims under strictly limited conditions is inconsistent with TSCA and that section 14 necessitates deleting those regulatory provisions.

B. <u>EPA Should Consider Requiring Generic Names for Trade Secret or</u> <u>Confidential Chemical Identities in Health and Safety Studies and Requiring</u> <u>Up-Front Substantiation of CBI Claims for Studies</u>

EPA already requires up-front substantiation for CBI claims in studies submitted under sections 4, 5, and section 8(e). ⁸⁵ EPA does not require up-front substantiation for CBI claims for submissions under section 8(d) ⁸⁶ or section 5(h)(4). ⁸⁷ It should require up-front submission of all CBI claims for chemical identities.

A key reason for EPA's current position that it must disclose trade secret or confidential chemical identities in studies is its belief that without some knowledge of what chemicals were studied, the public has no way to evaluate the study. Steve Owens, then Assistant Administrator for Office of Chemical Safety and Pollution Prevention, has said, "[a] health and safety study with the chemical name kept secret is completely useless to the public." This position is contradicted by EPA's findings in 1983, 1993, and 1994 that in some circumstances "[t]he specific chemical identity is not necessary to interpret a health and safety study," as explained in Section VI above.

As EPA previously recognized, in order to make studies meaningful to the public, it is not necessary to require disclosure of chemical identities in every case. Instead, requiring submission of structurally-descriptive generic names can provide sufficient information to make studies useful while still protecting trade secret or confidential identities. Such generic names can provide the public with detailed information about the structure of the chemical, thus allowing linkage to the scientific literature on similar chemicals and permitting an assessment of the suitability of study methods. In contrast, specific chemical names are sometimes of little value to the public, since there may be no published scientific literature on the specific chemical, particularly in the case of new or recently developed chemicals.

There is ample Congressional precedent for the disclosure of structurally-descriptive generic names instead of specific chemical identities. The use of such generic names is called for in section 5(d)(2), in EPCRA, and in SARA Title I. As noted above, the legislative history of the EPCRA generic name provision cited EPA's experience with generic names under TSCA with approval.

⁸⁵ 40 C.F.R. §§ 720.85(b)(3)(iv) (PMNs), 725.94 (MCANs), 790.7(c) (section 4 submissions), and 68 Fed. Reg. 33129, 33140 (June 3, 2003) (section 8(e) submissions).

⁸⁶ See 40 C.F.R. § 716.55.

⁸⁷ See 40 C.F.R.§ 723.50(l), 723.175(k).

⁸⁸ EPA press release, "EPA Removes Confidentiality Claims for More Than 150 Chemicals / Part of continuing effort to protect Americans' health by increasing access to chemical information" (June 8, 2011), available at http://yosemite.epa.gov/opa/admpress.nsf/a543211f64e4d1998525735900404442/9f7964fcbca3824a852578a900574cea!OpenDocument.

Aside from the examples cited above, EPA has numerous times required disclosure of generic names instead of specific chemical identities as a way of balancing the competing interests. EPA chose to require the use of generic names for entries in the confidential TSCA Inventory, ⁸⁹ even though "Congress did not seem to contemplate that the fact that certain chemical substances are manufactured or processed for commercial purposes would be claimed as confidential." EPA explained that in deciding to require the use of generic names it "had to balance the competing concerns of section 14 and sections 8(a) and 5(b)." EPA has adopted generic name requirements in its regulations implementing section 5, ⁹¹ section 8(b), ⁹² and EPCRA § 322. ⁹³

As articulated in the PMN and MCAN regulations, EPA has identified the key question as whether the specific chemical identity is "necessary to interpret a health and safety study." This is a different question than whether the public must have the chemical substance's CAS number in order to access the published toxicological literature of <u>other</u> studies on the same chemical substance. That makes sense, particularly with respect to recent PMN substances, which are highly unlikely to be the subject of published toxicological literature. In that context, a generic name can provide sufficient information to interpret that study.

Moreover, a generic name may be used to access the toxicological literature on structurally-related compounds. In many cases, a search on Toxline, a common tool for searching the toxicological literature, using a CAS number or CAS name will identify few, if any, studies. In contrast, searching on a generic name for the same chemical substance may identify a significant number of studies. This may be seen by searching on Toxline using specific chemical names, CAS numbers, and generic names for the same chemicals.

In 2009, EPA changed 530 chemical identities on the TSCA Inventory from confidential to non-confidential. EPA had previously associated generic names with those chemical substances. In many cases, a Toxline search for a generic name for a declassified substance identified more studies than did Toxline searches for the corresponding CAS number and CAS name. For example:

- EPA associated the generic name "alkyl salicylaldehyde" with benzaldehyde, 5-dodecyl-2-hydroxy-, CAS No. 77635-21-3.
 - o A Toxline search on "salicylaldehyde" identified 279 studies.
 - o Toxline searches on the CAS name and on the CAS number identified no studies.

^{89 40} C.F.R. § 710.7(f), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).

⁹⁰ Id. at 64590. See 44 Fed. Reg. 2242, 2255 (Jan. 10, 1979) (similar language in proposed PMN provision on generic names).

⁹¹ 40 C.F.R. §§ 720.80(a)(2), 721.1(c), 723.50(l)(2), 725.85(a)(3),); former 40 C.F.R. § 723.250(f)(2)(x), 49 Fed. Reg. 46066, 46088 (Nov. 21, 1984).

⁹² Former 40 C.F.R. § 710.7(e)(ii), 42 Fed. Reg. 64572, 64579 (Dec. 23, 1977).

^{93 40} C.F.R. § 350.5(f).

⁹⁴ 74 Fed. Reg. 37224 (July 28, 2009).

- EPA associated the generic name "silane, dichloro(chloralkyl)alkyl-" with silane, dichloro(3-chloro-2-methylpropyl)methyl-, CAS No. 1628-11-1.
 - A Toxline search on "dichlorosilane" identified 27 studies.
 - Toxline searches on the CAS name and on the CAS number identified no studies.
- EPA associated the generic name "disubstituted quinolone" with 2,3-quinolinedicarboxylic acid, CAS No. 643-38-9.
 - A Toxline search on the generic name identified 21 studies.
 - Toxline searches on the CAS name and on the CAS number identified one study.
- EPA associated the generic name "alkylpridinium halide" with pyridinium, 1-dodecyl-, bromide (1:1), CAS No. 104-73-4.
 - o A Toxline search on "alkylpridinium" identified 38 studies.
 - o Toxline searches on the CAS name and CAS number identified 13 studies.
- EPA associated the generic name "pyrimidinamine, disubstituted" for two of the declassified identities.
 - o A Toxline search on "pyrimidinamine" identified 118 studies.
 - One of the declassified chemical substances with that generic name was 2pyrimidinamine, 4,6-dimethoxy-, CAS No. 36315-01-2. Toxline searches on the CAS name and on the CAS number identified one study.
 - The other declassified chemical substance with that generic name was 2pyrimidinamine, 4-chloro-6-methoxy-, CAS No. 5734-64-5. Toxline searches on the CAS name and on the CAS number identified two studies.

In short, generally, a structurally-descriptive generic name is sufficient for interpreting a submitted health and safety study, and that same generic name can be more effective than the specific chemical name or CAS number for identifying studies on the same or related compounds in the toxicological literature.

C. <u>EPA Should Work With Industry and NGOs to Improve Development of</u> Generic Names

EPA has complained that "CBI procedures consume an inordinately large amount of Agency resources that may not be justified." In particular, negotiations between EPA and a submitter about appropriate generic names may be onerous. The solution is for EPA, industry, and NGOs to work together to improve the process for identifying appropriate generic names and thereby expedite those negotiations.

EPA has provided some guidance on how to develop generic names, ⁹⁶ but that guidance has not been updated in over 25 years. As EPA has recognized, the guiding principle should be that "[t]he proposed generic name must be only as generic as necessary to protect the identity of the particular chemical substance." Congress endorsed that principle in EPCRA and SARA

_

^{95 58} Fed. Reg. 7661, 7666 (Feb. 8, 1993).

⁹⁶ "Generic Names for Confidential Chemical Substance Identities," Appendix B to Vol. 1 of the Toxic Substances Control Act Chemical Substance Inventory (1985), http://www.epa.gov/opptintr/newchems/pubs/genericnames.pdf. ⁹⁷ Id. at 64591.

Title I, where it called for disclosure of "the generic class or category" rather than a highly-detailed generic name. The legislative history of that provision in EPCRA states:

The generic class or category of chemical may be defined as broadly as is needed to protect the specific chemical identity from disclosure, but, consistent with the purpose of this title to provide information to the community and the public, it should be defined no more broadly than necessary to afford such protection. 98

EPA now has decades of experience in developing generic names. It should work with industry and NGOs to memorialize that experience in the form of detailed guidance. Such guidance, reflecting the input of industry, will go a long way toward reducing the resources needed for determining appropriate generic names.

D. <u>EPA Should Allow CBI Claims for Chemical Identities in Studies Where</u> Appropriate

EPA has announced that "[w]here a chemical identity [in or underlying a study] does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment." As explained above, EPA should follow the requirements of section 14(a) and in appropriate cases accord CBI protection for those chemical identities. As it reviews studies with CBI claims for chemical identities (e.g., in its ongoing review of historical CBI claims), EPA should allow those claims, at least where substantiation of continuing CBI status is provided. EPA should consider requiring disclosure of an appropriate generic name as a condition for non-disclosure.

E. <u>EPA Should Allow CBI Claims for Chemical Identities in R&D Mixtures</u> Where Appropriate

Of particular concern to much of industry is the situation where product formulations under development are tested, then those studies are submitted under TSCA. In almost all cases, the formulations contain only existing chemical substances, but the combination of the particular components may be highly innovative. EPA has indicated that it expects to release to the public chemical identities in or underlying studies submitted under section 8(e) where the chemical identities appear on the public TSCA Inventory. Presumably, this includes mixtures of chemical substances, all of whose identities appear on the public Inventory. Where those mixtures are for R&D products, however, EPA should not require disclosure.

As explained in section III.F of this paper, section 14(b) of TSCA applies to a submitted study with respect to "any chemical substance **or mixture** which, on the date on which such study is to be disclosed has been offered for commercial distribution." A mixture that has not "been offered for commercial distribution" at the time of disclosure because it is R&D or has otherwise never been commercialized is not covered by that provision, even if its components are on the public Inventory. Accordingly, EPA should not disclose its components just because a

⁹⁹ 75 Fed. Reg. 29754 (May 27, 2010).

⁹⁸ H. Conf. Rep. No. 99-962 (1986) at 303, 1978 U.S.C.C.A.N. 3276, 3396.

study on that mixture has been submitted. EPA did disclose the components of such a mixture recently in connection with a section 8(e) submission by Proctor & Gamble, 8EHQ-94-13020. There the original submission indicated that the mixture was the subject of R&D.

CONCLUSION

EPA is incorrect in interpreting section 14(b) to require disclosure of trade secret or confidential chemical identities in or underlying most health and safety studies except where their disclosure would also reveal process or portion of mixture information. Instead, section 14(a) protects trade secret chemical identities, even in or underlying studies. Section 14(b) is directed at health and safety information, not trade secret or confidential chemical identities.

EPA should continue to balance the interest in disclosure of health and safety information with the interest in protecting trade secrets and confidential information. One way favored by Congress to do this balancing is to require development of generic names, which would be disclosed in lieu of specific chemical identities.

Available at http://www.epa.gov/oppt/existingchemicals/pubs/declassified/actions/6-8-2011/8EHQ-94-13020 89110000315.pdf.



September 15, 2016

Barbara Cunningham (7401M)
Deputy Director for Management and Pollution Prevention
Office of Pollution Prevention and Toxics
Environmental Protection Agency
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: <u>Initial Evaluation of the Amended TSCA Confidentiality Provisions</u>

Dear Barbara:

On behalf of the American Chemistry Counsel (ACC), I thought it would be useful to share with EPA ACC's initial ideas on how the various provisions of the amendments made to the Toxic Substances Control Act (TSCA) by the Lautenberg Chemical Safety Act (LCSA) should be interpreted. We would appreciate the opportunity to hear EPA's ideas as well and to discuss both perspectives. I look forward to our discussion on these provisions in the near future.

SUMMARY

This letter provides ACC's initial views about some of the key aspects of amended section 14 as they relate to confidential chemical identities. In summary:

- The LCSA amendments to section 14 essentially continue the statutory approach to protection of confidential chemical identities from disclosure embodied in the original TSCA.
- Section 14(a) is a reverse-FOIA provision which prohibits EPA from disclosing confidential business information (CBI) exempt from mandatory disclosure under exemption (b)(4) of the Freedom of Information Act (FOIA), except as provided elsewhere in section 14.
- Section 14(b) identifies limited exclusions from section 14(a). These exclusions continue to allow CBI claims for confidential chemical identities, even if contained within health and safety studies that must otherwise be disclosed.
- FOIA mandates disclosure; TSCA does not. To the extent that information excluded by section 14(b) is also exempt from mandatory disclosure under FOIA exemption (b)(4), EPA has discretion to disclose or withhold that information. EPA should continue to



balance the competing interests of public access to the CBI in health and safety studies and protection of trade secrets contained in those studies. Where a structurally descriptive generic name is provided, as is now mandated by section 14(c)(1)(C), disclosure of the specific chemical identity is not necessary. Thus, wherever structurally descriptive generic names are provided, EPA should not disclose confidential chemical identities covered by section 14(b).

• Section 14(g)(4) directs EPA to establish a unique identifier for each specific chemical identity for which it approves a request for protection from disclosure. EPA should not assign unique identifiers in a manner that reveals confidential chemical identities.

DISCUSSION

1. The LSCA Made Few Changes Relating to the Confidential Status of Chemical Identities Claimed as CBI

The amendments to section 14 did not affect the basic issue of whether confidential chemical identities must be protected from disclosure or must be disclosed. Instead, they primarily addressed the processes information submitters will follow when requesting protection from disclosure of CBI, and that EPA will use when evaluating those claims. Nothing in the legislative history of the LCSA suggests a congressional intent to alter the previous provisions as they relate to disclosure or protection of confidential chemical identities in health and safety studies submitted under TSCA.¹

Before the recent amendments, section 14(b) did not apply to CBI in health and safety studies that would reveal process information and that continues to be the case. However, an amendment clarified that among the process information that is excluded from section 14(b) (and which therefore is protected by section 14(a)) is "formulas (including molecular structures) of a chemical substance or mixture." The term "molecular structures" is a way of referring to chemical identities.² Thus, amended section 14(b) expressly protects confidential chemical identities from disclosure when the identities would reveal process information. This express protection does not imply, however, that confidential chemical identities that would not reveal process information are subject to section 14(b). EPA retains the discretion to protect confidential chemical identifies in other circumstances.

In light of the small substantive change to section 14(b), most aspects of the attached 2012 ACC White Paper, "TSCA Protects Confidential Chemical Identities in Health and Safety Studies from Disclosure," (White Paper) remain relevant.³ The White Paper reviews policy reasons why

¹ ACC acknowledges one exception to this point – namely the clear mandate to disclose what had been protected as CBI when CBI protections are withdrawn or cannot be maintained.

² Section 10(b) of FIFRA, which protects trade secrets from disclosure, similarly specifies that "formulas of products" may not be disclosed, even though health and safety studies must otherwise be disclosed. That provision has long been understood as precluding EPA from disclosing the confidential chemical identities of inerts in a pesticide formulation, even if mentioned in a health and safety study.

³ ACC submitted the White Paper to EPA on January 20, 2012, and discussed it with Assistant Administrator Jim Jones and his staff in a meeting on February 14, 2012.

EPA should protect confidential chemical identities from disclosure;⁴ interprets statutory provisions throughout TSCA that protect such identities from disclosure;⁵ shows how the legislative history of section 14(b) supports protection of confidential chemical identities; and reviews EPA's practices throughout its implementation of TSCA to protect those identities.

The White Paper recommends that EPA require up-front substantiation of CBI claims for confidential chemical identities and disclosure of structurally descriptive generic names for such identities. The amendments to section 14 effectively implement both of those recommendations.

2. Section 14(a) Prohibits Disclosure of CBI Not Subject to an Exception

It is helpful to recognize section 14(a) as a reverse-FOIA provision that prohibits disclosure of information exempt from mandatory disclosure under FOIA, except to the extent that other provisions of section 14 (such as section 14(b)) create exceptions to that prohibition. Congress enacted this and other reverse-FOIA provisions because "FOIA is exclusively a disclosure statute" and "does not give the authority to bar disclosure" because "Congress did not design the FOIA exemptions to be mandatory bars to disclosure." The point of a reverse-FOIA provision is to prohibit disclosure. Section 14(a) has counterparts in other federal regulatory statutes.

Accordingly, section 14(a) establishes the basic approach for deciding whether to protect confidential chemical identities from disclosure. That protection is mandatory except to the extent that an exception applies. This means that the exceptions should be read narrowly.

3. <u>Under Section 14(b), Confidential Chemical Identities in Health and Safety</u> Studies Are Protected from Disclosure

The LCSA made only minor changes to the exceptions in section 14(b) from the protection from disclosure provided by section 14(a). The meaning of those exceptions essentially has not changed.

In 2010, EPA announced its interpretations of the section 14(b) exceptions. ⁸ Generally, those interpretations indicated that EPA would not protect from disclosure chemical identities on the public Inventory (unless the identities revealed process or percentage of mixture information). In response, ACC submitted to EPA the attached White Paper disagreeing with certain EPA interpretations and policy changes. In particular, the White Paper maintained that under section 14(b)(1), health and safety effects information in studies submitted under TSCA is not protected from disclosure, but confidential chemical identities (whether or not on the confidential Inventory) in those studies are protected from disclosure.

⁴ One of those policy reasons was protection of trade secrets because of the economic value that they bring to the U.S. That reason was reiterated by the recent enactment of the Defend Trade Secrets Act of 2016, Pub. L. 114-153 (May 11, 2016) only a few weeks before enactment of the LCSA.

⁵ In some cases, the LCSA revised the subsections in which those provisions appear, but most or all remain in TSCA as amended.

⁶ Chrysler Corp. v. Brown, 441 U.S. 281, 285, 293-294 (1979).

⁷ E.g., Consumer Product Safety Act § 6(a)(2), 15 U.S.C. § 2055(a)(2).

⁸ 75 Fed. Reg. 3462 (Jan. 21, 2010) (confidential chemical identities submitted under section 8(e)); 75 Fed. Reg. 29754 (May 27, 2010) (confidential chemical identities in health and safety studies).

The legislative history of the LCSA's amendments to section 14(b) apparently referred to this debate:

[The Senate Committee bill] retains virtually verbatim the language of existing section 14(b)(1), relating to the disclosure of confidential information in the context of a health and safety study. The adoption of this provision of existing law does not signal the Committee's intent to agree or disagree with EPA's interpretation of the provision to date. Rather, it reflects the significant debate over the scope and interpretation of that provision, which could not be successfully resolved.⁹

However, Congress did enact new language relating to CBI contained in a health and safety study, new section 14(b)(1), which provides:

MIXED CONFIDENTIAL AND NONCONFIDENTIAL INFORMATION.—
Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

The Senate Committee Report commented on an earlier version of that language, stating:

The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.¹⁰

The House Committee Report made the same point:

Fifth, the legislation clarifies that while health and safety studies about a specific chemical substance or mixture are not eligible for protection as CBI, those studies cannot reveal data that would disclose formulas, including molecular structures, for chemical substances and mixtures whose protection as confidential has been justified to EPA. The Committee expects that redactions or the use of approved generic names or unique identifiers will be employed to meaningfully inform the public without comprising trade secrets.¹¹

This position is similar to that espoused by the EPA General Counsel in 1976, who opined that the 1972 version of FIFRA mandated the disclosure of effects information in health and safety studies submitted under FIFRA, but protected from disclosure "confidential ingredient

⁹ S. Rep. 114-67 (June 18, 2015) at 22, https://www.congress.gov/114/crpt/srpt67/CRPT-114srpt67.pdf.

¹¹ H.R. Rep. 114-176 (June 23, 2015) at 30, https://www.congress.gov/114/crpt/hrpt176/CRPT-114hrpt176.pdf.

statements" in those studies. 12 Other environmental statutes also require disclosure of effects information but protect confidential chemical identities from disclosure. 13

With this clarification in new section 14(b)(1), Congress clearly contemplated that not everything in a health and safety study is to be disclosed if it would otherwise be protected by section 14(a). It strongly suggests that confidential chemical identities otherwise protected by section 14(a) must be protected from disclosure.

In short, section 14 protects confidential chemical identities in health and safety studies submitted under TSCA, even if those identities are on the public TSCA Inventory.

4. Section 14(b) Does Not Mandate Disclosure of Health and Safety Studies

Amended section 14(b)(2) does not mandate disclosure of health and safety studies submitted under TSCA; instead, it provides simply that "Subsection (a) does not prohibit the disclosure of" certain health and safety studies and other specified information. FOIA does not mandate disclosure of such CBI either, due to exemption (b)(4). Because CBI in health and safety studies subject to section 14(b)(2) is neither protected from disclosure nor subject to mandatory disclosure, EPA must exercise its discretion in deciding whether or not to disclose such CBI.

Historically, EPA has exercised that discretion by balancing the competing interests of disclosure and protection against loss of trade secrets. In the context of health and safety studies submitted with PMNs, EPA has concluded that it will not protect confidential chemical identities from disclosure *unless* "[t]he specific chemical identity is not necessary to interpret a health and safety study."¹⁴ Where the specific chemical identity is unnecessary for that purpose, it will protect the CBI. When adopting this position, EPA explained:

In an attempt to meet both these concerns, EPA has chosen an approach that balances the need for confidentiality, the need to understand health and safety studies, and the provisions of TSCA...

Under § 720.90(c) of the rule, if any health and safety studies have been submitted for the chemical substance in question, the specific chemical identity will be held confidential only if disclosure would reveal confidential manufacturing or processing processes or the confidential proportions of substances in a mixture, or if the specific chemical identity is not necessary to interpret any of the studies ...

Companies that claim specific chemical identity confidential in their notices who wish to argue that knowledge of the specific identity is not necessary to interpret their health and safety studies are encouraged to choose generic names which are sufficiently specific to interpret their health and safety studies. **Sufficiently specific generic names will tend to**

_

¹² Opinion No. 76-8 (Mar. 5, 1976), 1976 WL 25230 (E.P.A.G.C.), quoted in the White Paper at p. 17.

¹³ See the White Paper at pp. 23-26; Resource Conservation and Recovery Act of 1976, Pub. L. 94-580 (Oct. 21, 1976), § 3007(b) (enacted 10 days after TSCA).

¹⁴ 40 C.F.R. § 720.90(c).

support arguments that disclosure of the specific chemical identity is not necessary to understand the study. 15

As amended by the LCSA, section 14(c)(1)(C) now mandates that any claim for protection of confidential chemical identities must include "a structurally descriptive generic name." With this new requirement, the balancing of interests should always favor protection of the CBI.

5. EPA Should Not Implement the Unique Identifier Provision to Reveal CBI

New section 14(g)(4) directs EPA to assign a unique identifier to any confidential chemical identity which it withholds from disclosure. This identifier must be unique, in contrast to a structurally descriptive generic name, which can apply to multiple chemical substances having a similar molecular structure. The purpose behind this provision an easy way of identifying all related CBI information that would be disclosed when a claim is withdrawn, denied, or when the criteria for protection are not met. However, the unique identifier must be applied very carefully so as not to inadvertently disclose confidential information. EPA must take care to protect links to company identities and information on commercialization when that information is claimed confidential.

Where the confidential chemical identity is already on the confidential Inventory, the accession number could serve as the unique identifier. There are no accession numbers for chemicals that are not on the Inventory, however, so accession numbers must only be one source among others for unique identifiers.

For example, many R&D chemicals are not on the TSCA Inventory. A PMN submitter must submit all health and safety studies on the PMN substance as part of the PMN, at which time the PMN substance does not have an accession number (and EPA would assign an accession number only if subsequent to the end of the PMN review period the PMN submitter were to submit a notice of commencement). In addition, chemicals being evaluated for their potential to be used as pesticides (subject to TSCA prior to application of FIFRA¹⁶) are typically not on the Inventory, and yet they may be the subject of submissions under section 8(e). If those pesticide candidates are successful, they would become subject to FIFRA and would never receive an accession number. For these chemicals, EPA would either have to assign a unique identifier other than an accession number, or delay assigning a unique identifier until such time, if ever, that it does assign an accession number.

¹⁵ 48 Fed. Reg. 21722, 21739-40 (May 13, 1983) (emphasis added). This resolution parallels the legislative history of section 5(d)(2), which directs EPA to identify PMN chemicals in Federal Register notices "by generic class" unless a more specific identification is required in the public interest. The Senate Report for an early TSCA bill with a provision which became section 5(d)(2) in a later bill explained that such a generic name, "coupled with the test results that are made available would be valuable to independent scientists who have knowledge of similar chemical substances and the toxicity characteristics that might be expected of a member of that same family. If the test results published vary significantly from the known toxicity of similar substances, then the independent scientist could have good reason to question the published results." S. Rep. No. 97-283 at 20 (1972). In other words, Congress contemplated that having a structurally descriptive generic name would enable the public to understand a study without the need to disclose confidential chemical identities revealed in the studies.

¹⁶ See 40 C.F.R. § 720.36(g).

In addition, as discussed in section 3 of this letter, a confidential chemical identity may be on the public Inventory. These chemicals will not have accession numbers either. Thus, EPA will have to derive unique identifiers for these chemicals as well.

Where EPA has agreed to protect from disclosure a confidential chemical identity that is on the public Inventory, it should not use the unique identifier to reveal that identity by applying it to public information that specifically identifies that chemical. For example, if it is a trade secret that chemical X (which is on the public Inventory) is in a formulated product that is the subject of study submitted to EPA under TSCA, and EPA has agreed to keep the identity of chemical X confidential with respect to that study, EPA should not apply the unique identifier to other public information that gives the specific chemical identity of chemical X. That would reveal the very information that EPA had agreed to keep confidential.

CONCLUSION

I look forward to discussing the paper with you and your staff.

Sincerely,

Christina Franz

Christina Inanz

Senior Director, Regulatory & Technical Affairs

Enclosure: ACC White Paper, "TSCA Protects Confidential Identities in Health and Safety

Studies From Disclosure" (Feb. 21, 2012)



Comments of the American Chemistry Council on CBI Claims for Underlying Data for Health and Safety Studies under TSCA

June 6, 2018

Christina Franz American Chemistry Council 700 Second Street, N.E. Washington, DC 20002 (202) 249-6406

Of Counsel: Mark N. Duvall Beveridge & Diamond, P.C. 1350 I Street, N.W. Washington, DC 20005 (202) 789-6000



EPA Should Accept CBI Claims for Underlying Data for Health and Safety Studies Submitted Under TSCA

EPA should balance the competing interests of public access to health and safety studies submitted under TSCA and protection of data compensation rights of the study submitters. It may do this under section 14 of TSCA by accepting substantiated claims that underlying data qualify for protection from disclosure under section 14(a). Disclosing the final study report while withholding the underlying data would provide the public with key information about the study while protecting the rights of data owners.

1. <u>Legal Framework Allowing Protection of Underlying Data from Disclosure</u>

EPA has discretion under section 14 to disclose the study reports for studies submitted under TSCA and to withhold from public disclosure the data underlying of those study reports that are submitted to EPA or which EPA otherwise obtains.

Subject to certain exceptions, the Freedom of Information Act (FOIA)¹ directs EPA to release to the public upon request the information submitted to it under its various statutes, including TSCA. Exemption 4, however, exempts from this mandatory disclosure obligation "trade secrets and commercial or financial information obtained from a person and privileged or confidential" (CBI).² This provision does not prohibit disclosure of such CBI, however.

Section 14(a) of TSCA as amended³ is a broad reverse-FOIA statutory provision that prohibits EPA from disclosing publicly information qualifying under FOIA exemption 4. Section 14(a) provides in part:

IN GENERAL.—Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5, United States Code, by reason of subsection (b)(4) of that section—

- (1) that is reported to, or otherwise obtained by, the Administrator under this Act; and
- (2) for which the requirements of subsection (c) are met.

Section 14(a) is itself subject to exceptions, however. Among them is section 14(b)(2), which provides in part:

INFORMATION FROM HEALTH AND SAFETY STUDIES.—Subsection (a) does not prohibit the disclosure of—

² 5 U.S.C. § 552(b)(4).



¹ 5 U.S.C. § 552.

³ Amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), Pub. L. 114-182 (June 22, 2016).

- (A) any health and safety study which is submitted under this Act with respect to—
 - (i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or
 - (ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and
- (B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

The phrase "does not prohibit the disclosure" leaves to EPA the discretion and decision regarding the extent to which it will disclose a health and safety study. TSCA "does not prohibit the disclosure" of a health and safety study containing CBI due to section 14(b)(2). On the other hand, FOIA does not mandate the disclosure of a health and safety study qualifying as CBI due to paragraph (b)(4). The clear implication is that EPA has discretion to decide to what extent it will or will not disclose health and safety studies containing CBI, such as underlying data.

Section 14(b)(5) does not preclude EPA from exercising discretion to withhold underlying data. It provides:

CERTAIN REQUESTS.—If a request is made to the Administrator under section 552(a) of title 5, United States Code, for information reported to or otherwise obtained by the Administrator under this Act that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5, United States Code.

As noted above, the basis for EPA's discretion would be its judgment in balancing competing interests, not because FOIA exemption 4 applies. EPA has previously exercised similar discretion in its regulations permitting CBI claims for chemical identity in health and safety studies submitted to support a PMN where a robust generic name is provided.⁴

2. The Competing Interests

When EPA exercises its discretion to decide to what extent to disclose a health and safety study, it should consider the competing interests at stake.

a. The Public Interest in Transparency of EPA Decision-Making

The public interest underlying section 14(b)(2) reflects the congressional intent that the basis for EPA's decision-making under TSCA should be transparent. As amended, section 26(i) requires EPA to make its decisions based on the weight of the scientific evidence, and section 26(h) directs EPA to make its decisions in a manner consistent with the best available science. Section 26(j)(4) requires EPA to make available to the public a list of



⁴ 40 C.F.R. § 720.85(a)(2), (b)(3).

the studies considered when completing risk evaluations. Collectively, these provisions are advanced by making the health and safety studies on which EPA relies in its decision-making available to the public.

As discussed below, however, the public interest in access to underlying data for submitted studies is limited when balanced against the commercial interest in protecting competitive data from disclosure.

b. The Commercial Interest in Protecting Competitive Data from Disclosure

Congress expressed concern that CBI in health and safety studies not be disclosed. The Senate Report for S. 697 (the Senate version of what became the LCSA) cautioned:

The Committee expects that EPA will ensure that health and environmental effects information from health and safety studies is disclosed, while appropriately protecting CBI contained within a study.⁵

Sometimes the CBI in a health and safety study to be protected is the specific identity of the chemical substance that is the subject of the study.⁶ To make this point, Congress added to an exception to section 14(b)(2) a reference to information that reveals "molecular structures." To ensure that the public would be able to understand studies for which the chemical identity is withheld as CBI, however, Congress in section 14(c)(1)(C) required a CBI claim for a chemical identity to include "a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public."

Sometimes the CBI in a health and safety study to be protected is competitive information, such as "company name or address, financial statistics, and product codes used by a company." In other instances the CBI in a health and safety study to be protected is, instead, the underlying data. EPA interprets "underlying data" to include "medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies." Another term for "underlying data" is "raw data." Sometimes underlying data



⁵ S. Rep. 114-67 (June 18, 2015) at 22.

⁶ Prior to enactment of the LCSA, EPA took the position that "[c]hemical identity is part of, or underlying data to, a health and safety study," citing 40 C.F.R. § 716.3 (regulatory definition of "health and safety study"), and thus that confidential chemical identities in a health and safety study submitted under TSCA must be disclosed except as provided in the exception to section 14(b)(2). Industry disagreed with this position, arguing that chemical identities in health and safety studies could be withheld as CBI more broadly. In amending section 14(b), Congress recognized but did not resolve this dispute. See S. Rep. 114-67 at 22.

⁷ See 40 C.F.R. § 716.55(a)(4) (allowing study submitters under section 8(d) to omit such information from a study). The provision purports to rely on FOIA exemption 6 for information related to personal privacy, but is instead corporate information. Under the Supreme Court's decision in *FCC v. AT&T, Inc.*, 562 U.S. 397, 408 (2011), however, corporate information is not eligible for exemption 6. The basis for this provision is actually exemption 4. This information is comparable to that excluded from the need for routine substantiation under section 14(c)(2).

^{8 40} C.F.R. § 716.10(a)(4).

⁹ The TSCA Good Laboratory Practice (GLP) regulations define "raw data" in 40 C.F.R. § 792.3 as follows: "Raw data means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the

appears in lengthy appendices to health and safety studies, and at other times underlying data remains in separate files that may or may not be submitted with the study report that is submitted to EPA under TSCA.

Underlying data submitted to EPA under TSCA may qualify as CBI under FOIA exemption 4. While it may not qualify as a trade secret, it is "commercial ... information obtained from a person;" thus, if it is also "confidential," it qualifies for FOIA exemption 4.¹⁰ Commercial information is "confidential" under Exemption 4 if its disclosure is likely "to cause substantial harm to the competitive position of the person from whom the information was obtained." EPA's disclosure of raw data from a study submitted under TSCA, including disclosure to the study submitter's competitors, can cause substantial competitive harm. ¹²

Congress recognized in section 4 that health and safety studies can have commercial value to study submitters; thus, underlying data is "commercial information." Section 4(c)(3(A) provides that persons who submit health and safety studies required by EPA may be entitled to "fair and equitable reimbursement" from other companies benefiting by such submission. This provision, like the corresponding provisions in FIFRA, provides a mechanism by which the study owner is owed a measure of data compensation by others who benefit by submission of the study–typically, competitors—by avoiding the need to submit an equivalent study themselves. ¹³

Even when the study report is disclosed, the underlying data may be "confidential," i.e., its disclosure may result in substantial competitive harm to the study owner. Often, it is the availability of underlying data that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data generator of the value of its investment in the underlying data. A study submitted under TSCA may also need to be submitted to a foreign regulatory agency. If EPA has made the



result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments."

¹⁰ See, e.g., *Public Citizen Health Research Group v. FDA*, 185 F.3d 898 (D.C. Cir. 1999); *Public Citizen Health Research Group v. FDA*, 704 F.2 1280 (D.C. Cir. 1983).

¹¹ See Critical Mass Energy Project v. NRC, 975 F.2d 871, 878 (D.C.Cir.1992) (en banc) (citing National Parks, 498 F.2d at 770).

¹² The raw data of a study not in the public domain qualifies as CBI when that data provides a commercial value to its owner. See, e.g., *Cohen v. Kessler*, No. 95-6140 (D.N.J. Nov. 25, 1996) (drug manufacturer had an express expectation of confidentiality when it submitted raw data to the FDA in support of its application for approval of a new bovine growth hormone and the FDA maintained this data with the strictest confidence; disclosure of raw data is likely to substantially harm company's competitive position because this is the type of information that its competitors would use in order to develop their own version of this bovine growth hormone without incurring the research and development costs). Also see U.S. Department of Justice Guide on FOIA exemption 4 at

https://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/exemption4_0.pdf

¹³ EPA has adopted rules implementing section 4(c)(3)(A) in 40 C.F.R. Part 791.

underlying data from that study public pursuant to section 14(b)(2), competitors would find it easier to use that study—without providing compensation to the original data owner to obtain data access or citation rights—to support their notification or registration of a substance under some foreign counterparts to TSCA.¹⁴

Any doubts EPA may have to whether underlying data qualifies as CBI may be resolved by review of the substantiation for its CBI claim provided by the study submitter under section 14(c)(3).

3. EPA Should Balance the Competing Interests by Allowing CBI Claims for Underlying Data

a. Section 14 Encourages Balancing of Competing Interests

Congress gave EPA discretion to decide to what extent to require health and safety studies to be disclosed, while protecting the CBI contained within those studies. This reflects the overall interest of Congress in section 14 of balancing the competing interests of transparency in EPA's decision-making and protection of CBI. The Senate Report explained:

In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under the section b(4) exemption of the Freedom of Information Act (FOIA) (i.e., "trade secrets and commercial or financial information obtained from a person and privileged or confidential") with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to maximize public availability of health and environmental information relating to chemical substances in commerce. Striking a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information on chemicals is essential to encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public. 15



¹⁴ EPA under FIFRA requires persons citing a study owned by a third party to affirm that they have the study owner's permission to cite the study or have offered to pay data compensation to the study owner. 40 C.F.R. § 152.93(b). Similarly, REACH Article 30 requires SIEF members to pay compensation to other members who own studies needed for registration. Some other counterparts to TSCA do not have such a provision, however. For example, Japan, the Philippines, and Taiwan do not. For them, simply providing a copy of the study, however obtained, may be sufficient and there is no obligation to affirmatively demonstrate that the notifier or registrant has data access privileges. Competitors to the original data generator may be able to obtain full copies of a study from EPA because EPA disclosed it under section 14(b)(2). Without underlying data, however, the study may not be deemed to meet the data requirement.
¹⁵ S. Rep. 114-67 (2015) at 21.

b. The Public Interest in Underlying Data Is Limited Where that Underlying Data Qualifies as CBI

As noted above, the public interest in underlying data is limited in that the human health and environmental results of studies can be made public in a manner to meet the public interest while still protecting the competitive commercial value of underlying data. This may be concluded by EPA's general practice of accepting a study report without submission of underlying data.

Members of the public who may want to review a study on which EPA makes its decisions would presumably have access to the final study report. As described in EPA's GLP regulations, a final report includes extensive information about the study. ¹⁶ Many studies submitted to EPA comply with the EPA GLP regulations, which require the Quality Assurance Unit to:

Review the final study report to assure that such report accurately describes the methods and standard operating procedures, and that the reported results accurately reflect the raw data of the study. 17

Accordingly, members of the public generally have sufficient information to understand the basis for EPA's decision-making if they have access to the final report.

Admittedly, underlying data fits within the definition of "health and safety study." TSCA defines "health and safety" to include "underlying information," and EPA has defined "health and safety study" to include "underlying data." The section 4 regulations, the section 8(d) regulations, and the PMN regulations require manufacturers to submit health and safety studies to EPA under some circumstances. Nevertheless, it is noteworthy than none of these regulations routinely requires study submitters to submit underlying data along with a final report. This is a clear indication that the final report communicates sufficient information about the potential health and environmental effects to the public when a company has submitted health and safety studies in which it has a commercial interest in protecting. 20



¹⁶ 40 C.F.R. § 792.185(a). All test rules and testing consent orders include a requirement to comply with the EPA GLPs, including this provision. Several significant new use rules provide that study reports must include the contents specified in that regulation. 40 C.F.R. §§ 721.537, 721.2122, 721.2584, 721.9928. ¹⁷ 40 C.F.R. § 792.35(b)(6).

¹⁸ TSCA § 3(8).

¹⁹ 40 C.F.R. §§ 716.3, 720.3(k), 725.3.

²⁰ ACC believes that making a final study report publicly available where the underlying data is CBI would comport with EPA's recent proposal regarding Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (April 30, 2018). In addition, where EPA relies on studies where the underlying data is CBI, EPA can access that underlying to confirm the methods, models, and approaches are based on validated procedures, accessible data, etc. If need be, EPA could contract with an independent third-party science reviewer to confirm those findings, although ACC believes this would likely be necessary only in unusual circumstances. EPA might also consider an approach followed under FIFRA where Data Evaluation Records of studies are made publicly available, but not the full study. See, e.g.,

https://archive.epa.gov/pesticides/chemicalsearch/chemical/foia/web/pdf/010501/010501-050.pdf

The section 4 GLP regulations require underlying data to be archived, ²¹ but the testing requirements only call for submission of a final study report²² and reference to where the raw data are located. ²³ EPA's FIFRA GLPs have a corresponding provision. ²⁴ EPA does not routinely require persons subject to a section 4 testing requirement to submit underling data along with a final report.

The section 8(d) regulations state:

In general, health and safety studies, as defined in § 716.3, on any substance or listed mixture listed in § 716.120, that are unpublished are reportable, i.e., must be submitted or listed. However, this requirement has limitations according to the nature of the material studied, so that: ...

(4) **Underlying data**, such as medical or health records, individual files, lab notebooks, and daily monitoring records supporting studies **do not have to be submitted** initially. EPA may request underlying data later under § 716.40.²⁵

Similarly, while the PMN regulations require submission of health and safety studies, ²⁶ EPA does not require submission of underlying data, saying:

The data may be submitted in aggregate or summary form; underlying data, such as individual measurements, are not required.²⁷

Instead, EPA concluded that a study report will be sufficient:

If the data do not appear in the open scientific literature, the submitter must provide a full report. A full report includes the experimental methods and materials, results, discussion and data analysis, conclusions, references, and the name and address of the laboratory that developed the data.²⁸

c. <u>Balancing the Competing Interests Favors Protection of Private</u> Competitive Interests

EPA balanced the public and private interests in disclosure or non-disclosure of chemical identities in health and safety studies submitted to support PMNs, concluding that the private interest outweighed the public interest where the study submitter provided a sufficiently robust generic name.²⁹ Similarly, EPA should balance the public and private interests in disclosure or non-disclosure of underlying data submitted with studies where



²¹ 40 C.F.R. § 792.33(f) (study director must transfer all raw data to archives by the close of the study).

²² See, e.g., 40 C.F.R. §§ 799.5085(i), 799.5087(i), 799.5089(i).

²³ See, e.g., 40 C.F.R. §§ 795.120(e)(13), 797.1600(e)(12).

²⁴ 40 C.F.R. § 160.185.

²⁵ 40 C.F.R. § 716.10(a)(4) (emphasis added).

²⁶ 40 C.F.R. § 720.50.

²⁷ 48 Fed. Reg. 41132, 41136 (Sept. 13, 1993).

²⁸ 40 C.F.R. § 720.50(a)(3)(i).

²⁹ 40 C.F.R. § 720.85(a)(2), (b)(3); 48 Fed. Reg. 21722, 21739-40 (May 13, 1983).

the study submitter provides a final report which discusses most or all of the information called for by the TSCA GLP regulations and substantiates the CBI claim.

In adopting the section 8(d) exemption for underlying data, EPA explained:

The final requirements represent the Agency's effort to reduce the burden of the rule while still obtaining the most useful studies for our assessments. EPA received many good comments that allowed the Agency to identify the studies that were most burdensome to submit and least useful for its assessments Therefore, the Agency has added to the exemptions originally proposed. The final rule has the following overall exemptions: ... (7) underlying data such as medical records, monitoring data, and lab notebooks (unless the EPA requests the data later, by personal letter).³⁰

In its words, EPA considers underlying data to be "least useful for its assessments." EPA reserved the possibility that it might need underlying data, in which case it could request the underlying data by letter, facility archive inspection/audit, or, potentially, by subpoena. In practice, however, EPA has rarely, if ever, requested underlying data. This long-time experience is strong evidence that, generally, the scientific need for underlying data is low for studies conducted according to GLP regulations. This suggests that the public interest in having access to underlying data for health and safety studies where a final report of a GLP study is provided is also low.

In contrast, the private interest in preserving the compensability of underlying data for studies when submitted under foreign counterparts to TSCA is high. Underlying data can qualify as CBI, and Congress put a premium on preserving CBI in health and safety studies.

EPA should weigh the competing interests and conclude that it should not disclose underlying data submitted or otherwise obtained under TSCA where the study submitter can substantiate its CBI claim and it provides a study report.



³⁰ 47 Fed. Reg. 38780, 38781 (Sept. 2, 1982).

³¹ See 40 C.F.R. § 716.40.

Updates to the TSCA Section 5 (New Chemicals) Procedural Regulations (40 CFR part 720) Summary of the Notice of Proposed Rulemaking (NPMR) for Stakeholder Outreach November 2020

EPA is seeking early input from stakeholders on the Notice of the Proposed Rulemaking (NPRM) to update the TSCA Section 5 procedural regulations, currently under development in the Office of Pollution Prevention and Toxics. The goals of the NPRM are to:

- Align the current regulations with the 2016 Lautenberg amendments,
- · Clarify certain regulatory requirements, and
- Improve the PMN process so that its more predictable, transparent, and efficient.

Background:

- The regulations at 40 CFR part 720 specify the procedures for EPA's review of new chemical submissions under TSCA section 5.
- The regulations were not updated following the 2016 Lautenberg amendments.

Inefficiencies of the Current Section 5 Notice Review Process:

Over 99% of new chemical notices are amended with new information, often multiple times, and usually late in the review period. The frequent amendments and the reliance on suspensions creates an unpredictable, and inefficient review process. Examples include:

- Excessive 'rework' of cases: When information is omitted from notices, the EPA assessors apply conservative assumptions and use default values to determine risk. In response to the identification of potential risks, submitters often will in turn amend their notices with additional information, causing re-work and overall delay in the review.
- 'Late' information: After submitting a notice, submitters may request several months to gather new information (e.g., conduct a new study) to address the potential risks identified in the risk assessment. Once the new information is submitted, EPA must then take time to rework the risk assessment, which extends the review period well beyond what TSCA specifies.

Regulatory Changes Under Consideration:

EPA is seeking input on the potential changes to 40 CFR part 720, including but not limited to:

- Potential PMN form (CDX) improvements
 - Specific information from the June 2018 "Points to Consider" document could be reflected as new fields in CDX.
- Improvements addressing the inefficiencies described in the examples above.

Overall Question:

• What improvements do you recommend to address the inefficiencies in the new chemical notice review process described above?

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 11/2/2020 7:15:39 PM

To: Passe, Loraine [Passe.Loraine@epa.gov]

CC: Dekleva, Lynn [dekleva.lynn@epa.gov]; Le, Madison [Le.Madison@epa.gov]; Master, Barbora

[Master.Barbora@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]

Subject: RE: EPA request for early input on proposed changes to 40 CFR part 720

Dear Loraine,

Thank you for your email and your interest in our views. Unfortunately, the dates you have identified are quite full on my calendar with most items that I cannot move, with the exception of Friday, the 13th. I am wide open on the 13th except for the 11-1 time slot.

Thank you very much,

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o) 301-580-6562 (c) Christina Franz@americanchemistry.com

From: Passe, Loraine [Passe.Loraine@epa.gov] **Sent:** Thursday, October 29, 2020 5:38 PM

To: Franz, Christina

Cc: Dekleva, Lynn; Le, Madison; Master, Barbora; Sullivan, Andrew

Subject: EPA request for early input on proposed changes to 40 CFR part 720

Dear Christina:

As a representative of the new chemicals industry subject to the Toxic Substances Control Act (TSCA), the Environmental Protection Agency (EPA) is seeking your early input on a proposed rule under development in the Office of Pollution Prevention and Toxics (OPPT). The rule would amend 40 CFR part 720 which specifies the procedures for EPA's review of new chemical submissions under TSCA Section 5. The purpose of the rule is to improve the efficiency of EPA's review process and to align its processes and procedures with the new statutory requirements under the Lautenberg Amendments. The rulemaking seeks to increase the quality of information initially submitted in new chemical notices and improve the Agency's processes to reduce unnecessary rework in the risk assessment, and ultimately, the length of time that new chemicals are under review.

We would like to schedule a 30-minute session to hear important feedback from you on the proposal during this early stage of development. Would you kindly reply to this email by November 4th and provide three 30-minute blocks that you are available during the following scheduling window: November 10^{th} , 11^{th} , 12^{th} , or 13^{th} . We will be back in touch shortly to confirm the meeting time.

Thank you for your timely response. We look forward to talking with you.

Kind Regards,

Loraine

Loraine Passe, Chief Risk Management Branch 1 New Chemicals Division Office of Pollution Prevention and Toxics U.S. Environmental Protection Agency Phone: (202) 564-9064

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist is for use by American Chemistry Council staff and member representatives in the conduct of American Chemistry Council-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to American Chemistry Council-sponsored meetings. The Checklist is not exhaustive and does not address antitrust issues relating to activities other than American Chemistry Council meetings. Participants in American Chemistry Council meetings also should be thoroughly familiar with: (1) "Antitrust Guide for American Chemistry Council Committee Members"; and (2) "General Principles Applicable to the Structure and Operations of Committees." Both of these documents may be found in the American Chemistry Council Directory.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- have an American Chemistry Council staff representative at each American Chemistry Council-sponsored meeting (unless an exception has been authorized by the appropriate American Chemistry Council vice president);
- consult with an attorney from Legal Shared Services on all antitrust questions relating to American Chemistry Council-sponsored meetings;
- limit meeting discussions to agenda topics (unless additional topics have been approved by the appropriate American Chemistry Council staff representative); and
- provide each member company representative and American Chemistry Council staff representative attending an American Chemistry Councilsponsored meeting with a copy of this checklist, and have a copy available for reference at all American Chemistry Council-sponsored meetings.

RECORDKEEPING:

- have an agenda and minutes which accurately reflect the matters which occur;
- provide agendas and minutes to Legal Shared Services for review and approval in advance of distribution; and
- fully describe the purposes and authorities of all task groups, work groups, ad hoc or other standing committee subgroups in the minutes of the appropriate parent committee.

VIGILANCE:

 protest against any discussion or meeting activities, which appear to violate this checklist; dissociate yourself from any such discussion or activities and leave any meeting in which they continue.

Revised 3/80 (single page version) Reformatted 1/89 MDB; 6/96 SKR; 4/97 PGM

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- individual company prices, price changes, price differentials, markups, discounts, allowances, credit terms, etc.;
- individual company data on costs, production, capacity, inventories, sales, etc.;
 and
- industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

 rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- company bids on contracts for particular products; company procedures for responding to bid invitations; and
- matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/6/2020 2:40:03 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: Re: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Sent from my iPad

On Oct 6, 2020, at 9:52 AM, Dekleva, Lynn <dekleva.lynn@epa.gov> wrote:

I will mention it but prefer to remove it from the agenda.

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina < Christina_Franz@americanchemistry.com>

Sent: Monday, October 5, 2020 6:49 PM **To:** Dekleva, Lynn <dekleva.lynn@epa.gov> **Subject:** RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Thanks, Christina

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: Monday, October 05, 2020 3:47 PM

To: Franz, Christina

Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Lynn

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina < Christina Franz@americanchemistry.com >

Sent: Monday, October 5, 2020 3:25 PM **To:** Dekleva, Lynn < dekleva.lynn@epa.gov **Subject:** RE: TSCA Section 5 EPA Meeting

Hi Lynn--

Ex. 5 Deliberative Process (DP)

thanks!

From: Dekleva, Lynn [dekleva.lynn@epa.gov]
Sent: Monday, October 05, 2020 3:19 PM

To: Franz, Christina

Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Lynn Dekleva, Ph.D.

Associate Deputy Assistant Administrator for New Chemicals Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency 1201 Constitution Ave., NW Washington, DC 20460 (202) 564-3895 (202) 845-6261 (cell) dekleva.lynn@epa.gov

----Original Appointment----

From: Franz, Christina < Christina Franz@americanchemistry.com >

Sent: Friday, October 2, 2020 8:22 PM

To: Dekleva, Lynn

Subject: FW: TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

-----Original Appointment-----

From: Franz, Christina

Sent: Thursday, October 1, 2020 12:58 PM **To:** Franz, Christina; TSCA Section 5 Group

Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William

Shade; Keller, Laura H; Grove, Scott Lee; Jon Gerber; Kerry Coy; Elizer, Emily B

Subject: TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

Formal agend to follow in the next few days.

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/5/2020 10:48:35 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Thanks, Christina

From: Dekleva, Lynn [dekleva.lynn@epa.gov] Sent: Monday, October 05, 2020 3:47 PM

To: Franz, Christina

Subject: RE: TSCA Section 5 EPA Meeting

Hi Christina,

Ex. 5 Deliberative Process (DP)

uegaras

Lynn

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina < Christina_Franz@americanchemistry.com>

Sent: Monday, October 5, 2020 3:25 PM
To: Dekleva, Lynn <dekleva.lynn@epa.gov>
Subject: RE: TSCA Section 5 EPA Meeting

Hi Lynn--

Ex. 5 Deliberative Process (DP)

From: Dekleva, Lynn [dekleva.lynn@epa.gov] Sent: Monday, October 05, 2020 3:19 PM

To: Franz, Christina

Subject: RE: TSCA Section 5 EPA Meeting

Ex. 5 Deliberative Process (DP)

Lynn Dekleva, Ph.D.

Associate Deputy Assistant Administrator for New Chemicals Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency 1201 Constitution Ave., NW Washington, DC 20460 (202) 564-3895 (202) 845-6261 (cell) dekleva.lynn@epa.gov

----Original Appointment----

From: Franz, Christina < Christina Franz@americanchemistry.com>

Sent: Friday, October 2, 2020 8:22 PM

To: Dekleva, Lynn

Subject: FW: TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

----Original Appointment----

From: Franz, Christina

Sent: Thursday, October 1, 2020 12:58 PM **To:** Franz, Christina; TSCA Section 5 Group

Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon

Gerber; Kerry Coy; Elizer, Emily B **Subject:** TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Ex. 6 Conference Code

Formal agend to follow in the next few days.

result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/5/2020 7:24:56 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]
Subject: RE: TSCA Section 5 EPA Meeting

Hi Lynn--

I will send the agenda shortly. Let me clarify though -- are you wanting to schedule this with Teams? That is fine if you do and we can work with that. Usually we use Webex, but I want to include the correct information on the agenda. If you have the information I should include on the agenda, please forward and I will list it there before sending to you.

thanks!

From: Dekleva, Lynn [dekleva.lynn@epa.gov] Sent: Monday, October 05, 2020 3:19 PM

To: Franz, Christina

Subject: RE: TSCA Section 5 EPA Meeting

If you have information you would like to share, I can send a Microsoft teams mtg. We will likely have a high level discussion on the default project. Not sure we will have anything to share by Thursday.

Lynn Dekleva, Ph.D.

Associate Deputy Assistant Administrator for New Chemicals Office of Chemical Safety and Pollution Prevention U.S. Environmental Protection Agency 1201 Constitution Ave., NW Washington, DC 20460 (202) 564-3895 (202) 845-6261 (cell) dekleva.lynn@epa.gov

----Original Appointment----

From: Franz, Christina < Christina _ Franz@americanchemistry.com >

Sent: Friday, October 2, 2020 8:22 PM

To: Dekleva, Lynn

Subject: FW: TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

-----Original Appointment-----

From: Franz, Christina

Sent: Thursday, October 1, 2020 12:58 PM **To:** Franz, Christina; TSCA Section 5 Group

Cc: Hartigan, Suzanne; Howard, Brett; Braun, Robert; Catherine J Shelp; Mavian, Kari (K); Hoff, Mary Ann; Muellner, Mark; Willard, Travis L; Nicole Bechtold; Hunley, Jackie R; Roesh, Denise M; Marcia Levinson; Carrie Mcmichael; DOMUSH, HILARY L; Clark, Emily; Sandra Podolak; Joseph Skulsky; William Shade; Keller, Laura H; Grove, Scott Lee; Jon

Gerber; Kerry Coy; Elizer, Emily B **Subject:** TSCA Section 5 EPA Meeting

When: Thursday, October 8, 2020 2:30 PM-3:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Ex. 6 Personal Privacy (PP) - conference code/call in number

Formal agend to follow in the next few days.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 10/1/2020 4:52:09 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: RE: Section 5 Discussion

Yes, Lynn. I will send a meeting invite to the section 5 work group today to secure the time. I'll also forward that invite to you so that you can send it to the people at EPA that you would like to attend. I'll put together a formal agenda to share with you first before finalizing and sending to the attendees. I will likely send that to you tomorrow or Monday. Does that work for you?

Thanks,

Chrisitna

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002

202-249-6406 (o)

Ex. 6 Personal Privacy (PP) - personal phone

Christina Franz@americanchemistry.com

From: Dekleva, Lynn [dekleva.lynn@epa.gov] Sent: Thursday, October 01, 2020 11:55 AM

To: Franz, Christina

Subject: RE: Section 5 Discussion

Can we schedule something next Thursday 8-Oct from 2:30 -3:30? I have a recurring meeting during that time so I know the key individuals will be available during this time slot.

Lynn Dekleva, Ph.D.
Associate Deputy Assistant Administrator for New Chemicals
Office of Chemical Safety and Pollution Prevention
U.S. Environmental Protection Agency
1201 Constitution Ave., NW
Washington, DC 20460
(202) 564-3895
(202) 845-6261 (cell)
dekleva.lynn@epa.gov

From: Franz, Christina < Christina Franz@americanchemistry.com>

Sent: Tuesday, September 29, 2020 11:38 AM **To:** Dekleva, Lynn <dekleva.lynn@epa.gov>

Subject: Section 5 Discussion

Hi Lynn,

Apologies for the delay getting this list to you for Section 5 discussion. These are the topics we'd like to discuss. These include the two you mentioned. Please feel free to add others you would like to discuss that you may not have mentioned when we spoke. We know your time available is difficult to secure, but we hoped for an hour to an hour and a half if that might work with your schedule.

- OCSPP Reorganization
- Safety Data Sheet Requirements on section 5 submissions
- EPA section 5 defaults
- 40 CFR 720 revisions
- Access to engineering and health assessment reports
- EPA's selection of analogues
- Is a 2020 EPA Stakeholder Meeting on Section 5 Planned?

Thank you,

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o)

Ex. 6 Personal Privacy (PP) - personal phone

Christina Franz@americanchemistry.com

NOTICE: This email originated from a source outside of the American Chemistry Council. Do not click any links or access attachments unless you are expecting them, and know that the content is safe.

From: Franz, Christina [Christina_Franz@americanchemistry.com]

Sent: 9/29/2020 3:38:10 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]

Subject: Section 5 Discussion

Flag: Follow up

Hi Lynn,

Apologies for the delay getting this list to you for Section 5 discussion. These are the topics we'd like to discuss. These include the two you mentioned. Please feel free to add others you would like to discuss that you may not have mentioned when we spoke. We know your time available is difficult to secure, but we hoped for an hour to an hour and a half if that might work with your schedule.

- OCSPP Reorganization
- Safety Data Sheet Requirements on section 5 submissions
- EPA section 5 defaults
- 40 CFR 720 revisions
- Access to engineering and health assessment reports
- EPA's selection of analogues
- Is a 2020 EPA Stakeholder Meeting on Section 5 Planned?

Thank you,

Christina

Christina Franz

Senior Director, Regulatory & Technical Affairs American Chemistry Council 700 Second St., NE Washington, D.C. 20002 202-249-6406 (o)

Ex. 6 Personal Privacy (PP) - personal phone

Christina Franz@americanchemistry.com

From: Walls, Michael [Michael_Walls@americanchemistry.com]

Sent: 5/13/2020 5:38:27 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Tiwari, Ritesh [tiwari.ritesh@epa.gov];

Richard E. Engler, Ph.D. [rengler@lawbc.com]

CC: Gale, Kat [Kat_Gale@americanchemistry.com]

Subject: Thank you!

Lynn, Tale, Ritesh and Rich: I wanted to drop you a quick note of thanks for your participation and engagement on today's GlobalChem discussion on the new chemicals program. It was a very informative session – hopefully it will help promote some more robust submissions for consideration! I very much appreciate your taking time from your schedules to help our member companies better understand how the section 5 requirements work and why.

I hope you are all well. Take care! Mike

From: Walls, Michael [Michael_Walls@americanchemistry.com]

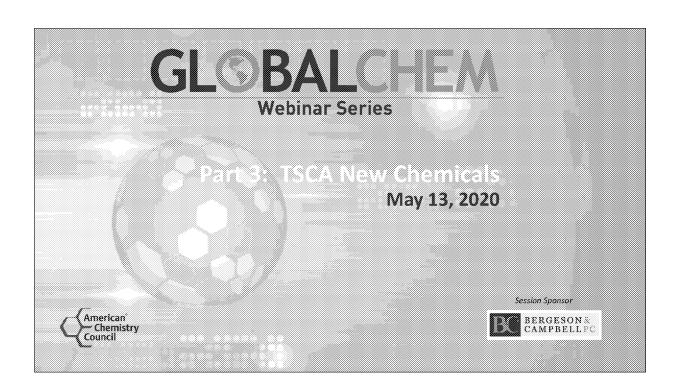
Sent: 5/13/2020 3:03:08 PM

To: Dekleva, Lynn [dekleva.lynn@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Tiwari, Ritesh [tiwari.ritesh@epa.gov];

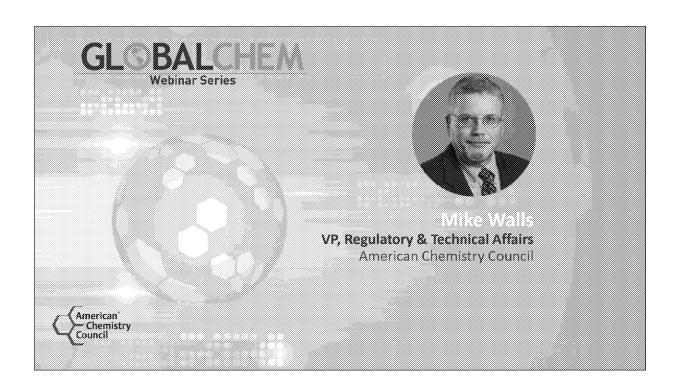
Richard E. Engler, Ph.D. [rengler@lawbc.com]

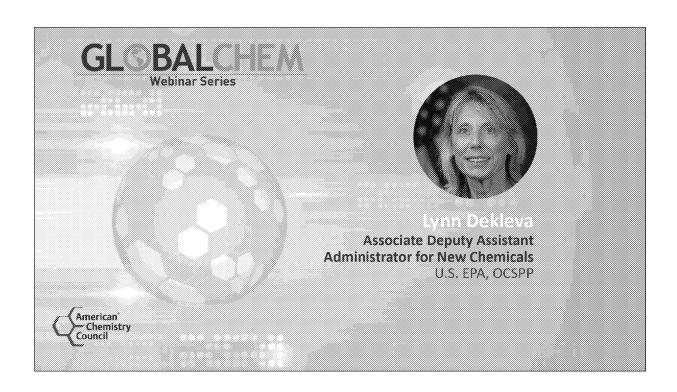
Subject: Final Slide Deck for Today's GC Part 3 Webinar **Attachments**: Part 3_TSCA New Chemicals_FINAL.PPTX

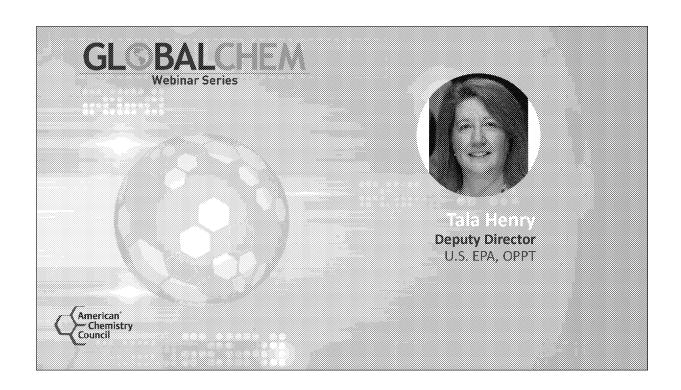
And now reflecting Ritesh's slides. Thanks to all of you!

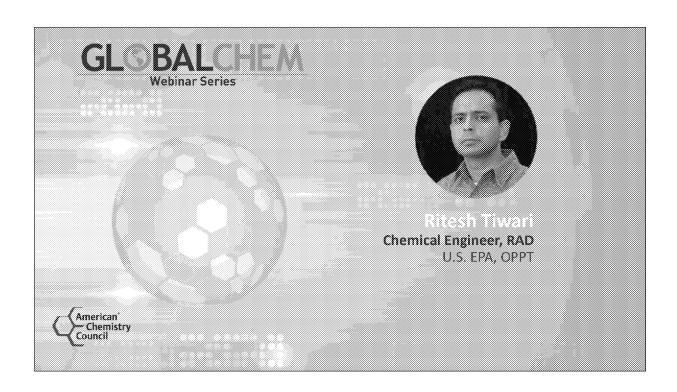


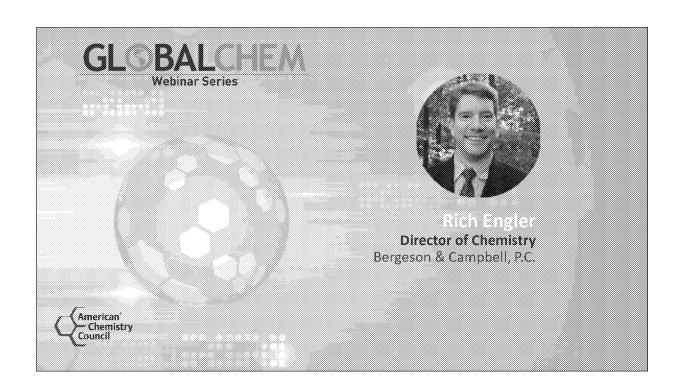


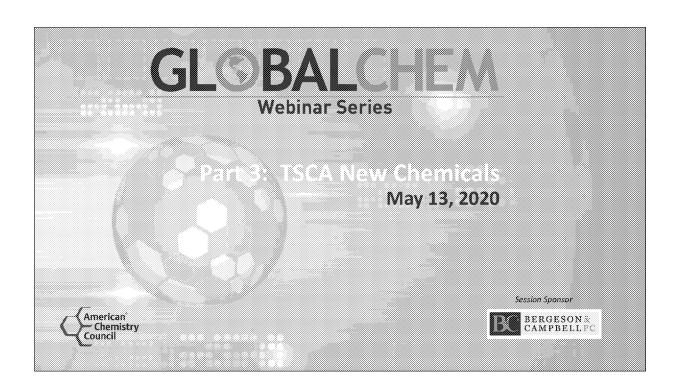












2016 TSCA section 5 Amendments

- Recognized critical role of section 5 in innovation and competitiveness
- Significant changes:
 - EPA must have sufficient information to make a decision
 - Requires attention to sensitive subpopulations
 - Reinforces transparency objective



Implementation Considerations

- Number of submissions
- Pace of reviews
- Scientific basis for decisions
 - Statutory requirements to apply best available science, using weight of the scientific evidence
- Process improvements



New Chemicals

Lynn Ann Dekleva
Associate Deputy Assistant Administrator
for New Chemicals

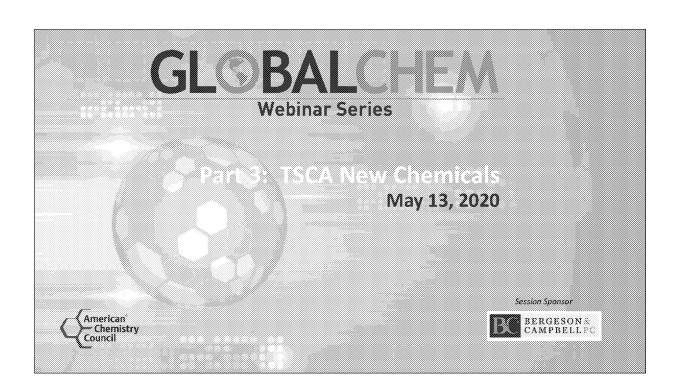
(DateFirm)

New Chemical Process Improvements

- Lean Activities
- Automation of Manual Processes
- Upgraded Case Tracking
- Deployment of Dedicated Resources
- Enhanced Submitter Engagement
- Utilization of Unilateral Orders
- Greater Transparency

{DateTime}





GlobalChem May 13, 2020 TSCA New Chemical Review Science Approaches

Tala R. Henry, Ph.D.

Deputy Director

Office of Pollution Prevention & Toxics

U.S. Environmental Protection Agency

New Chemical Hazard Assessment: Approach

- Data Preference: Chemical-specific test data > Analogue data > Modeled data
- Submitted data/studies: "Submitted health and environmental effects data/studies: Only requirement is for existing data in the possession or control of the submitter" per 40 CFR § 720.45
- EPA receives little data; in vitro, short-term >>> in vivo, subchronic/chronic

Analogue Identification

- Analogue Data: EPA Considers:
 - Physical-chemical properties (e.g., log K_{ow}, water solubility, and melting point), presence and position of reactive functional groups, etc.
 - Potential metabolites or degradates (e.g., hydrolysis products)
 - TSCA New Chemicals Program (NCP) Categories
 - Structural alerts for toxicity
 - Identify hazards associated with the category and/or structural alerts

Analogue Identification

- Analogues Identified:
 - To characterize hazards
 - To identify Points of Departure for quantifying risks
 - Even when data are submitted on the new chemical (rare to get robust set of hazard endpoints)
 - By SUBMITTER, EPA chemists, or EPA toxicologists

Analogue Identification: Search Tools

- EPA's Analogue Identification Methodology (AIM)
 - https://www.epa.gov/tsca-screening-tools/analog-identification-methodology-aim-tool
- NLM's ChemIDPlus
 - https://chem.nlm.nih.gov/chemidplus/
- OECD's QSAR Toolbox
 - http://www.oecd.org/chemicalsafety/risk-assessment/oecd-qsar-toolbox.htm
- EPA CBI databases
 - within AIM and Johem on EPA's CBI LAN

The Analog Identification Methodology (AIM) is a software program that facilitates analog analysis and data identification in support of chemical assessment or read-across approaches

Key characteristics of the program include:

Ability to conduct comprehensive structural analysis of chemicals using over 700 individual atoms, groups and super fragments indexed in a predefined database

Uses structural analysis to match potential analogs from an inventory of over 86,000 chemicals with publicly available measured data and links to the data sources

Ability to recode defined substitutions or exclusion rules for the refinement of analog search strategies

ChemIDplus is a free, web search system that provides access to the structure and nomenclature authority files used for the identification of chemical substances cited in National Library of Medicine (NLM) databases. ChemIDplus also has structure searching and direct links to resources at NLM, federal agencies, U.S states, and scientific sites. The database contains more than 400,000 chemical records, of which over 300,000 include chemical structures.

Analogue Data Sources

- EPA IRIS: Integrated Risk Information System
- EPA PPRTVs: Provisional Peer-Reviewed Toxicity Values
- EPA ChemView for HPVIS and full 8e studies
- EPA Comptox for ACToR and Comptox in vitro bioassay data; can also be used for analogues/read-across
- EPA NCELS: New Chemical Exposure Limits
- EPA CBI databases: AIM and JChem

- ATSDR Toxicological Profiles:
- CalEPA Chemicals Database
- ECHA Registered Substances Database
- HERA Project: Human and Environmental Risk Assessment
- INCHEM: Internationally Peer reviewed Chemical Safety Information
- OECD Existing Chemicals Database: HPV SIDS Assessments
- HSDB (tox summary data) and ChemIDPlus

Information Submitters Should Consider / Provide

- Justification for use of the analogue for the endpoint(s) identified, e.g., structural and biological.
- Full chemical name and CAS numbers of all analogues.
- Clear structural representation of all analogue(s).
- Full studies for any analogues, if available, to better ensure efficient consideration by EPA.

Information Submitters Should Consider/Provide

- Whether the structure of the new chemical substance has any structural alerts.
- Whether the new chemical substance has been submitted to/reviewed by another international agency.
- Explanation or rationale for why any toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation.
- Particle size/droplet size information for the new chemical substance would aid the assessment of respirability.
- Statement about the applicability of *in silico*, *in vitro*, or other non-vertebrate test data for use with evaluating the new chemical substance.

Whether the structure of the new chemical substance has any structural alerts

EPA's initial hazard flag.

Whether the new chemical substance has been submitted to/reviewed by another international agency 🛘 If data in ECHA Database, EPA will look there.

Explanation or rationale for why any toxicity information is not relevant for the intended use of the chemical substance could inform and expedite EPA's evaluation \Box refine exposure pathways/routes

Particle size/droplet size information for the new chemical substance would aid the assessment of respirability.

in silico, in vitro, or other non-vertebrate test can inform evaluation their chemical substance.

Innovative Assessment Approaches

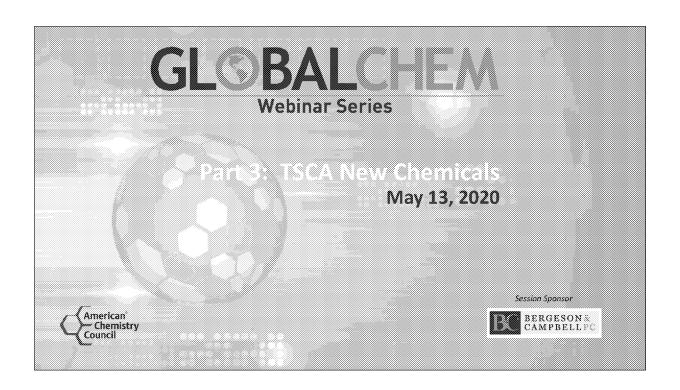
- Draft interim science policy for skin sensitization, replaces animal testing with new approach methodologies (NAMs)
- Lung Effect Categories with industry participation and engagement
 - Short-term reactive process: Polycationic Substances (Cationic Binding) & General Surfactants
 - Longer-term physical process: Insoluble Polymer Lung Overload
- Working with ACC panel members to develop a proposed respiratory sensitization framework for newer isocyanate chemistries

Innovative Assessment Approaches: Use of NAMs

- OPPT has utilized various NAMs to exclude chemical substances from specific chemical categories (e.g., polymer lung overload)
 - On April 1, 2020, EPA issued a proposed rule to revoke a significant new use rule (SNUR) for a new chemical substance, based on the results of a biosolubility study. See: https://www.govinfo.gov/content/pkg/FR-2020-04-01/pdf/2020-06442.pdf
 - The original SNUR would have required a subchronic inhalation toxicity study in order to
 use the chemical substance in a manner inconsistent with the original new chemical
 substance submission
 - Measured Biosolubility Data and refined manufacturing process information demonstrated the chemical would not present a hazard concern for lung overload

GlobalChen 2020

Thank You QUESTIONS?

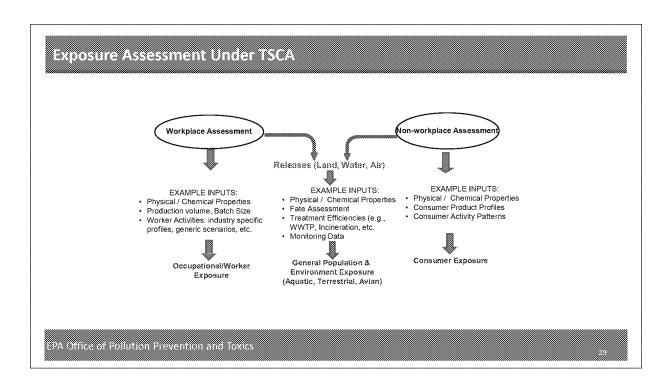


Global Chem
May 13, 2020

EPA's Tools and Methods for
Workplace Exposure and Environmental Release Assessments
Ritesh Tiwari

Contents

- 1. Exposure assessment under TSCA
- 2. Occupational exposure and environmental release assessment
- 3. Typical releases and exposures in a chemical process
- 4. Hierarchy of approaches used for estimating release and exposure assessments
- 5. Tools and methods for estimating environmental releases and workplace exposures
- 6. Critical data, defaults and assumptions
- 7. Refinements of estimates based on level of information provided by PMN submitter
- 8. Important data / information frequently not provided



Occupational Exposure and Environmental Release Assessment

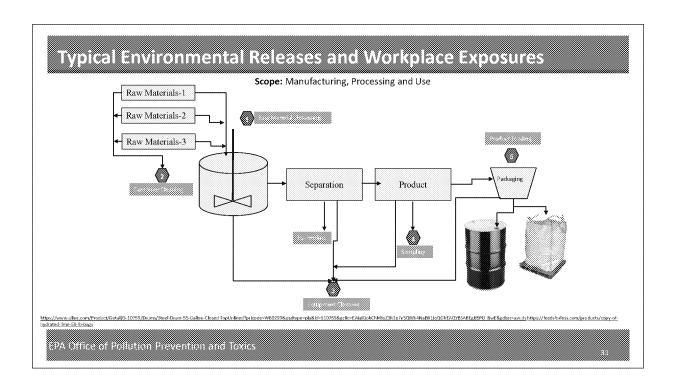
 Scope of assessment (e.g., manufacturing, processing, industrial/commercial use, distribution, and disposal)

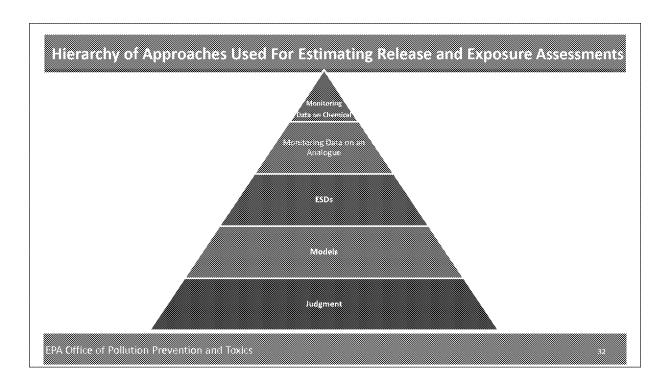
Environmental Releases

- Media: Air (stack, fugitive), Water (treatment, surface water, etc.), Land, Incineration, other (deepwell injection)
- Quantity: Mass per time (kg/site-day)
- Frequency (days/year)
- Location (postal zip code, city, NPDES or discharge permit number, etc., if known)

Occupational Exposures

- Route: Inhalation (vapor, mist, particulate), dermal (liquids, solids)
- Concentration (ppm, mg/m³) and dose (mg/day, mg/kg-day)
- Frequency (days/year)
- Population: Workers, including potentially exposed or susceptible subpopulations





Tools and Methods for Estimating Environmental Releases and Workplace Exposures

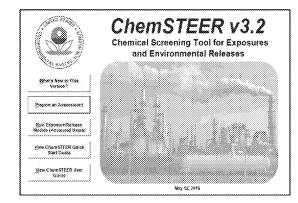
- Emission Scenario Documents (ESDs)
- Chemical Screening Tool for Exposures and Environmental Releases (ChemSTEER)
- Past PMN Submissions and Professional Judgment

Emission Scenario Documents (ESDs)

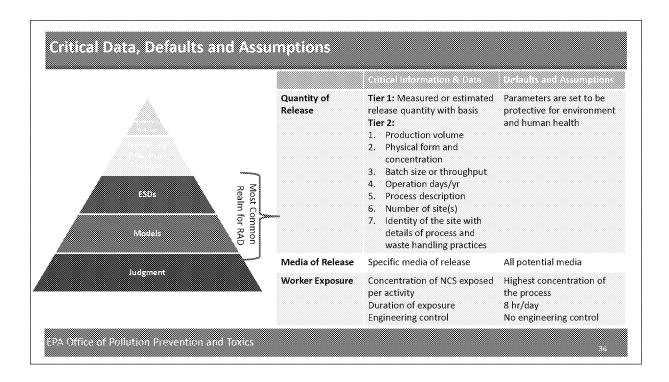
- 12 published ESDs (via OECD WPEA) and 48 Generic Scenario (GS) Documents
- ESDs are developed from published literature, industry-supplied information, including information from premanufacture notices (PMNs) and then reviewed by the OECD WPEA and other participants
 - Contents
 - Process Description
 - Mass Balance Data For Process / Operation
 - Release and Exposure Models
 - General Facility Estimates and other Default Values
 - · Estimation Equations and Example Calculations
 - Examples
 - · Use of Textile Dyes
 - Application of Radiation Curable Coatings, Inks and Adhesives
 - Use of Metalworking Fluids

OECD WPEA: Organisation for Economic Co-operation and Development , Working Party on Exposure Assessment (WPEA),

ChamSTEER version 3.2

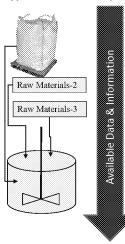


- A suite of peer-reviewed / established methods and models used to estimate workplace exposures and environmental releases of new and existing chemicals
- ~18 GS are fully integrated
- Version 3.2 includes new near-field / far-field model



Refinements of Estimates Based on Information Provided by PMN Submitter

Hypothetical Example: Unloading of compounded resin during processing of solid additive for plastic converting



		Differen Guntafo Registroney	Release Programme Programme	Air	Water	Land	Incineration
PV= 25000 kg/site-yr	2004 Plastic Converting GS	0.9	137	٧	٧	٧	٧
Day of operation, along with PV	GS & info from submission	0.5	250	٧	٧	٧	٧
*Baghouse with 99% efficiency, disposing to landfill, along with days of operation, and PV	GS & additional Info from submission	0.5	250	0.005	NO	0.495	NO

^{*}Basis of estimates and supporting documents are required

37

https://www.ulfne.com/Product/Detail/S-10756/Dumm/Steel-Dump-SS-Galion-Closed Too-Unlines for inote-wib22928.earthous-pulsakid=S-107598.earth=EAM Cob/Unline/ZRL2/PS-GW/MASELLS-GC/SEA/WIS-SEELSED. Buc Espain-craw.du https://www.intes.com/products/coop-ol-hydrated-coop-ol-hydrated-coo

Critical Data & Information Frequently Not Provided

Process description: A description of each manufacture (including import), processing, and use operation, including

- · The number and identity of sites where the new substance will be manufactured, processed, or used
- Physical forms and concentrations of the substance
- Maximum batch size (if batch process), daily throughput (if continuous process)
- · Days of operation per year
- Container type, capacity, cleaning procedure and frequency

NCS Release Estimates: Activities or points of releases of NCS

- · Estimated or measured quantity of environmental releases with basis of estimates
- Frequency of releases
- · Media of release

NCS Worker Exposure: Activities leading to worker exposure

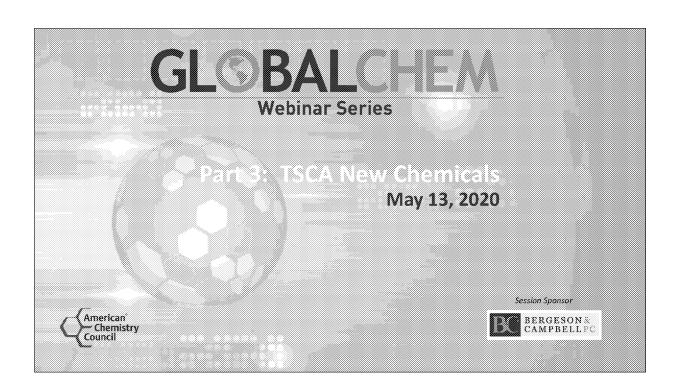
- · Physical form and estimated or measured concentration to which workers may be exposed, with basis of estimates
- · Number of workers exposed
- Duration of exposure

Engineering Controls: Technical description with basis for reported efficiency

Waste Disposal: Environmental licenses or permits and Waste Disposal Information. How is waste (including cleaning and process waste) disposed (e.g., on-site waste water treatment, POTW, incineration, landfill, etc.)

Conclusion

Data and information provided by submitter inform the reasonableness and accuracy of the estimates and can reduce rework





BERGESON & CAMPBELL PC

GlobalChem Webinar Series Part 3: TSCA New Chemicals

May 13, 2020

Richard E. Engler, Ph.D Bergeson & Campbell, P.C. Washington, D.C. www.lawbc.com

Ordino Berges in 8 Campusk, Fr.C. Ad Repto Reserved



Significant New Use Rules (SNUR)

- SNURs are up since the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg)
- Prior to 2016, 10-20% of premanufacture notices (PMN) were regulated (Section 5e or non-5e SNURs)
- Immediately after enactment
 - > >90% valid PMNs were receiving "may present" determinations with Section 5e orders

Or CoCO Bengasian & Olympical Fr. C., Ad Rephili Russerice



Solutions

- Polymer exemption flag
- Non-order SNURs
 - Reduces the need for orders, but still represent regulations and a burden on the supply chain (recordkeeping, Section 12(b), Chemical Data Reporting (CDR) threshold)
- Changes in what is "reasonably foreseeable"
 - Routine use of gloves, goggles, and general dermal protection in industrial settings
 - Requirement to specify "impervious" gloves
- Currently, about half of the PMNs are receiving orders/SNURs

Dische Burgeuer II. Genedauf, die G. Ad Pfigure Bassers ;



Suggestions for the U.S. Environmental Protection Agency (EPA)

- Explain better its reasoning on what is reasonably foreseeable
- Give better guidance on how a submitter can limit what EPA foresees
 - > Level of supporting evidence

Unabbe Burgasen i Genedasi, ih Olika Pagua Rusurva s

8.6